



Furiex[®]

THE POWER OF
ADVANCEMENT

2011

Furiex Pharmaceuticals, Inc.
Annual Report

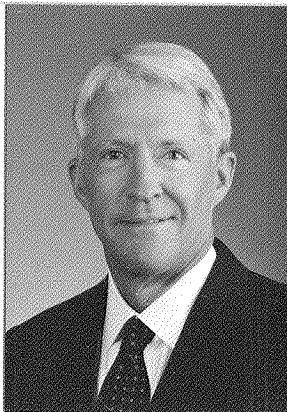
ADVANCING PROMISING THERAPIES TO MARKET FASTER

GROWING ASSET VALUE

Furiex Pharmaceuticals, Inc. is a drug development company applying innovative strategies to increase the value of drug candidates by advancing them rapidly to market. We invest in novel early stage candidates that address medical conditions with significant unmet needs, then progress them to key value inflection points before forming collaborations with commercial biopharmaceutical companies.

Our small nimble team of experts use innovative study designs that enable quick and effective decisions and accelerate drug development. Furiex's model has generated a diversified pipeline of two Phase III-ready compounds in development, one compound in Phase III with a collaborator and two marketed products with commercial partners.





Fred N. Eshelman, Pharm.D.



June S. Almenoff, M.D., Ph.D.

TO OUR FELLOW STOCKHOLDERS:

2011, our first full year as an independent company, has been extremely productive. We have executed on our business strategy and accomplished the goals that we set out at the time of our spinout from Pharmaceutical Product Development, Inc., or PPD, in mid-2010. Importantly, our development work has created two high quality Phase III-ready assets, and we gained exclusive license rights to these assets. With respect to our marketed, partnered portfolio, we saw a successful trajectory in the sales of Nesina® in Japan, as well as important regulatory progress for both Nesina® and Priligy®. Our ending cash balance for 2011 was approximately \$44 million—in line with our projected spend. Since our spinout from PPD, we have created considerable stockholder value and have increased our visibility in the investment and scientific communities.

Now that we have brought all of our pipeline assets through Phase II development, we are able to make strategic decisions about how to create the greatest value for our portfolio. We believe that this can be accomplished by prioritizing our resources to progress MuDelta to Phase III as rapidly as possible. To this end, we are investing in manufacturing and study start-up in order to support the possibility of initial patient dosing in mid-2012. We are in partnering discussions about MuDelta with a number of companies, and look forward to providing updates on our overall development strategy later this year.

PORTFOLIO HIGHLIGHTS FOR 2011

Pipeline Products in Clinical Development

MuDelta is a novel Phase III-ready drug that we are developing for the treatment of diarrhea-predominant irritable bowel syndrome, or IBS-d, a condition with high unmet medical need. In 2011, we:

- Acquired full exclusive license rights from Janssen Pharmaceutical, N.V., or Janssen, to develop and commercialize MuDelta;

Now that we have brought all of our pipeline assets through Phase II development, we are in a position to make strategic decisions to create the greatest value for our portfolio.

- Obtained Fast Track designation from the U.S. Food and Drug Administration, or FDA, based on unmet medical need for IBS-d;
- Completed a large randomized-double-blind Phase II Proof-of-Concept trial, demonstrating favorable efficacy and safety in patients with IBS-d; and
- Held an End-of-Phase II meeting with the FDA, which has provided us with a clear regulatory path forward to a New Drug Application, or NDA.

JNJ-Q2 is a novel Phase III-ready broad-spectrum fluoroquinolone antibiotic that has potent coverage against important drug-resistant pathogens including methicillin-resistant staphylococcus, or MRSA. In 2011, we:

- Acquired full exclusive license rights from Janssen to develop and commercialize JNJ-Q2;
- Held successful End-of-Phase II meetings with the FDA and E.U. regulators; and
- Obtained favorable qualitative results from our study for community-acquired bacterial pneumonia, even though we terminated the study early.

Our data support Phase III-readiness in both serious skin infections and community-acquired bacterial pneumonia indications, providing a clear competitive advantage over other antibiotics in development. We are continuing to seek to out-license or partner JNJ-Q2, and have made a strategic decision to limit further development spend, thereby allowing us to focus our resources on progressing MuDelta.

Marketed, Partnered Products

- In 2011, we recognized approximately \$4.5 million in royalty revenue from our partnered products, Priligy and Nesina. Our royalty revenue continues to exhibit strong growth driven by sales of Nesina in Japan. Royalty revenue grew by \$3.2 million, an increase of 246% from 2010.

Priligy® (dapoxetine), which is currently marketed by Janssen, is the first and only medicine specifically indicated for treatment for premature ejaculation.

- In January 2012, the European Commission recommended the approval of Priligy in more than 20 European countries where the drug had not yet been approved.

Nesina® (alogliptin), which is marketed by Takeda Pharmaceuticals Company Limited, or Takeda, is a selective DPP-4 inhibitor for Type 2 diabetes that is currently approved in Japan and is under NDA review with the FDA. In 2011:

- Takeda filed several regulatory submissions in the United States including the resubmitted NDAs for alogliptin and for alogliptin in fixed-dose combination with pioglitazone which have a PDUFA action date of April 25, 2012; and an NDA for a fixed-dose combination of alogliptin with metformin;
- Nesina received supplemental approvals in Japan, allowing its use as add-on therapy to two commonly prescribed diabetes treatments; and
- Takeda launched Liovel®, a fixed-dose combination tablet of Nesina and Actos® (pioglitazone HCl), in Japan.

LOOKING AHEAD

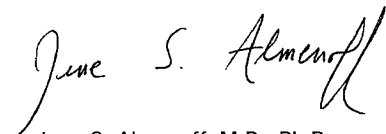
We are excited about the potential for our products to improve the health of millions of patients. 2012 could be a pivotal year for Furiex, because we anticipate success for the following catalytic events:

- Nesina, U.S. approval (which would trigger a \$25 million milestone) and E.U. submission (which would trigger a \$10 million milestone);
- Priligy, potential re-structuring of our deal with Janssen including the possibility of involving another collaborator; and
- Potential collaborations for MuDelta and JNJ-Q2.

We thank each of you, our fellow stockholders, for your support. We also wish to acknowledge the efforts and performance of our team, whose work has significantly enhanced the value of our pipeline. We look forward to updating you on our progress through the upcoming year.



Fred N. Eshelman, Pharm.D.
Chairman

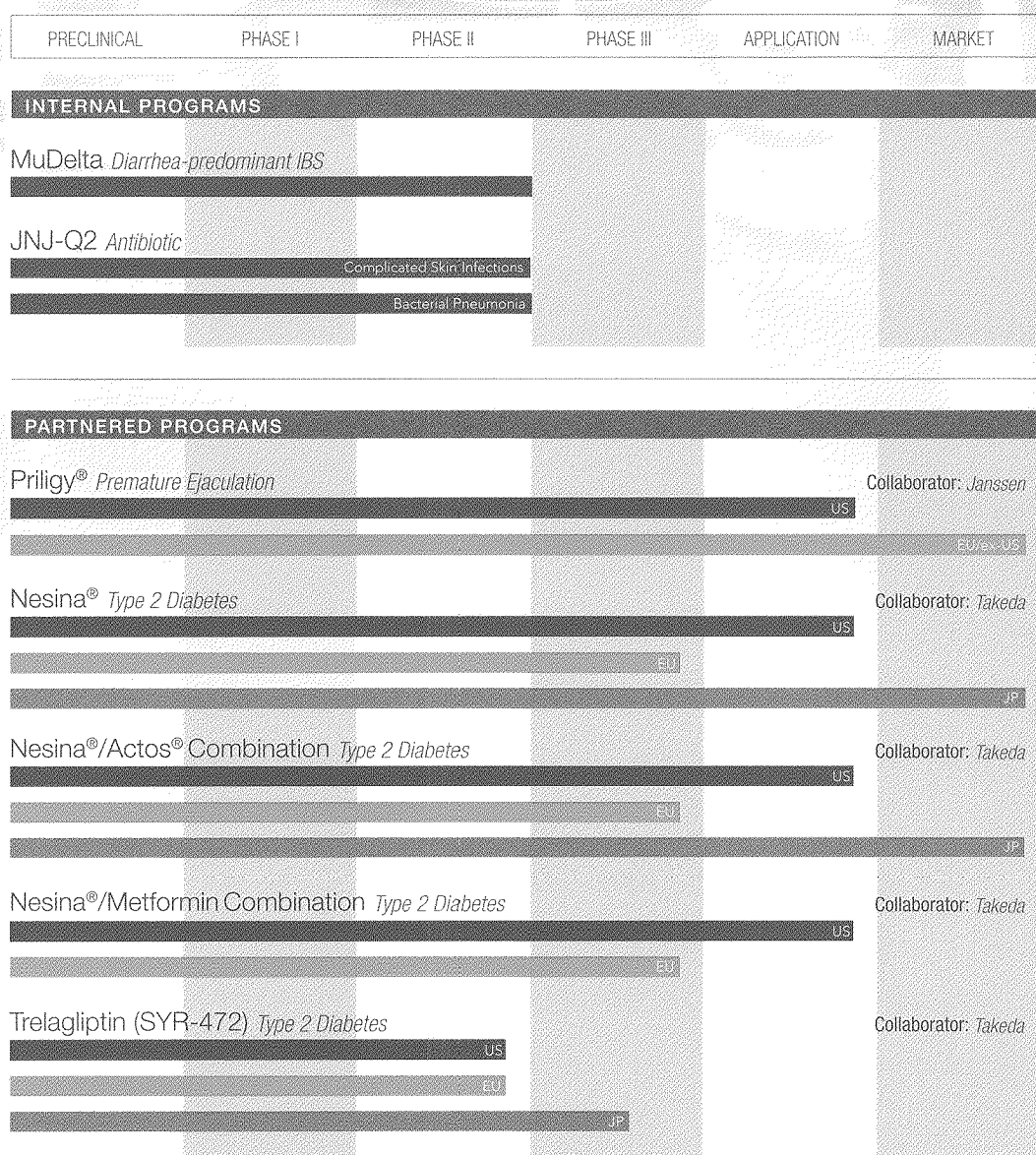


June S. Almenoff, M.D., Ph.D.
President and Chief Medical Officer

Furiex®

Pharmaceuticals | Fast. Focused. Expert.

Furiex has a robust and diversified drug pipeline that includes two marketed products and three programs in development across multiple therapeutic areas.



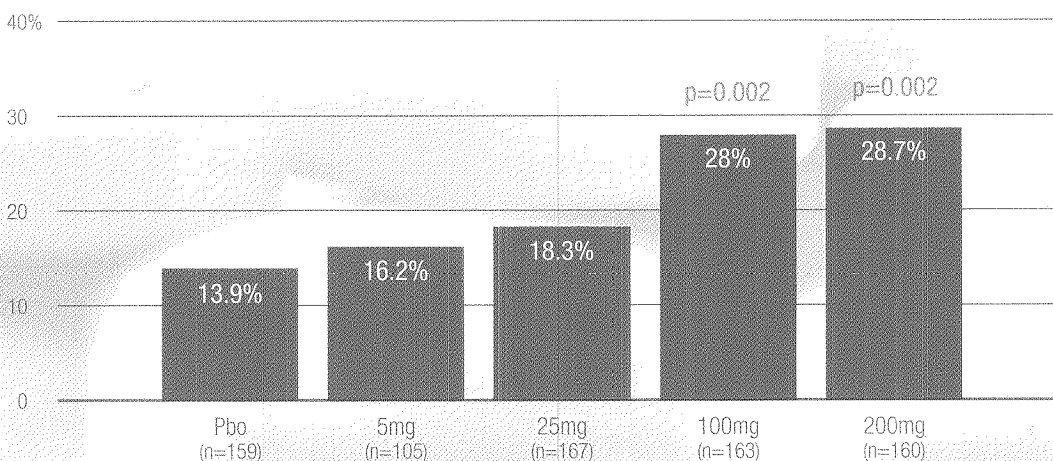
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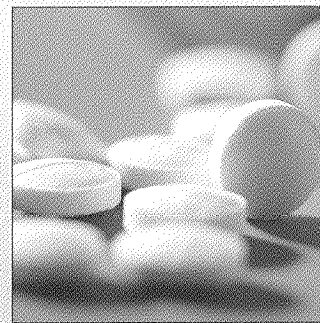
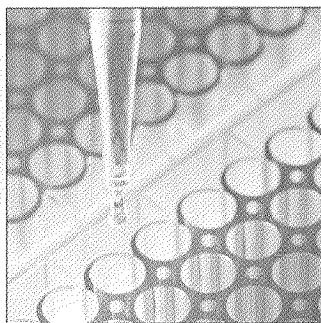
MuDelta is a Phase III-ready, first-in-class, locally-acting mu opioid receptor agonist and delta opioid receptor antagonist we are developing for treatment of diarrhea-predominant irritable bowel syndrome, or IBS-d.

In vivo studies indicate that the activity of MuDelta at the two different opioid receptors controls GI function as well as decreases pain, and potentially mitigates the constipating effect of unopposed mu agonism. MuDelta is locally active in the gut with very limited systemic bioavailability, thus potentially decreasing central nervous system effects and other systemic side effects associated with therapies currently used to manage IBS-d.

Responder Analysis: 12 Week Composite Endpoint

Percent Daily Responders





IBS-d is an underserved market as there are currently no unrestricted, approved products on the market either in the U.S. or European Union that are indicated for chronic treatment of IBS-d.

Furiex has successfully completed a Phase II study establishing the safety and efficacy of an oral formulation of MuDelta in patients with IBS-d. The study achieved statistically significant results for the primary endpoint of improvements in baseline stool consistency and abdominal pain at week 4 as well as a number of key secondary endpoints. MuDelta also demonstrated durable efficacy in improving IBS diarrhea and pain symptoms throughout the 12-week treatment period. MuDelta was well-tolerated and had a favorable safety profile.

The MuDelta development program has an agreed-upon, clear regulatory path forward with the FDA, and has been granted fast-track status by the FDA in acknowledgment of the potential for MuDelta to address a significant unmet medical need for patients with IBS-d. Furiex has a license agreement with Janssen, under which Furiex has exclusive global rights for development and commercialization of the product.

28m

DIARRHEA-PREDOMINANT IRRITABLE BOWEL SYNDROME AFFECTS APPROXIMATELY 28 MILLION PATIENTS IN THE UNITED STATES AND FIVE MAJOR EUROPEAN UNION COUNTRIES.



NESINA®

(ALOGLIPTIN)

A new oral drug for the treatment of Type 2 diabetes. Alogliptin is a DPP-4 (dipeptidyl peptidase-4) inhibitor that slows the inactivation of incretin hormones GLP-1 (glucagon-like peptide-1) and GIP (glucose-dependent insulintropic peptide), which play a major role in regulating blood glucose levels and have the potential to improve pancreatic beta-cell function.

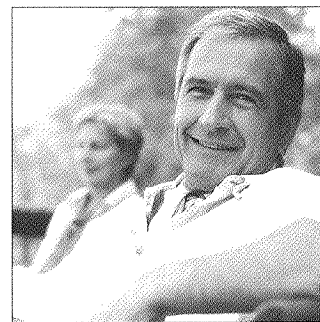
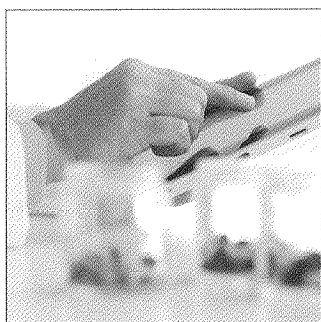
Nesina® (alogliptin) is a DPP-4 inhibitor. DPP-4 inhibitors are a relatively new class of drugs for the oral treatment of Type 2 diabetes (T2D), a chronic condition estimated to affect 4 percent of the world population by 2030. Alogliptin slows the inactivation of incretin hormones GLP-1 (glucagon-like peptide-1) and GIP (glucose-dependent insulintropic peptide), which play a major role in regulating blood glucose levels and have the potential to improve pancreatic beta-cell function.

In a clinical study of drug-naïve patients with inadequately controlled T2D, alogliptin was well-tolerated and significantly improved glycemic control without raising the incidence of hypoglycemia. Alogliptin was also found to be effective and well-tolerated in the treatment of T2D in elderly patients.

Nesina is being developed and marketed by Takeda Pharmaceuticals. In April 2010, Takeda received regulatory approval from Japan's Ministry of Health, Labour and Welfare for Nesina, and it is now being sold in Japan. Takeda has resubmitted a new drug application with the U.S. Food and Drug Administration, and the Prescription User Fee Act, or PDUFA action date has been set for April 25, 2012. Furiex has rights to royalties and sales-based milestones from Takeda for the sale of Nesina in Japan as well as regulatory milestones, royalties and sales-based milestones upon marketing approval of Nesina in other countries.

\$34b

GLOBALLY, THERE ARE AN ESTIMATED 283 MILLION PEOPLE WITH TYPE 2 DIABETES. WORLDWIDE SALES OF ANTI-DIABETIC TREATMENTS IN 2010 WERE \$34.4 BILLION.



NESINA FRANCHISE IS BEING DEVELOPED AND MARKETING BY TAKEDA PHARMACEUTICALS

Alogliptin/Actos® Combination

Takeda is developing a combination therapeutic using Nesina (alogliptin) and Actos (pioglitazone HCl) in a single tablet for the treatment of Type 2 diabetes. Pioglitazone is a thiazolidinedione that directly targets insulin resistance, a condition in which the body does not efficiently use insulin it produces to control blood glucose levels. It is approved in adults for the treatment of Type 2 diabetes as an adjunct to diet and exercise. Takeda received regulatory approval from Japan's Ministry of Health, Labour and Welfare for the alogliptin/pioglitazone fixed-dose combination and it is now being sold in Japan under the brand name Liovel®. This is the first Type 2 diabetes treatment option that includes a DPP-4 inhibitor and a thiazolidinedione. In July 2011, Takeda resubmitted a new drug application with the U.S. Food and Drug Administration for the alogliptin/pioglitazone combination and the PDUFA action date has been set for April 25, 2012. Furiex is entitled to receive royalties on product sales.

Alogliptin/Metformin Combination

Alogliptin/metformin is a fixed-dose combination therapy which combines the benefits of alogliptin with metformin in a single tablet, for the treatment of Type 2 diabetes. Metformin is a member of the biguanide class of oral hypoglycemics and is the usual first-line therapy in addition to diet control and exercise. Metformin improves hyperglycemia primarily by suppressing glucose production by the liver. Takeda submitted a new drug application to the U.S. Food and Drug Administration in November 2011 and is conducting Phase III studies for a potential filing in the E.U. in 2012. Furiex is entitled to receive royalties on product sales.

JNJ-Q2

JNJ-Q2 is a novel broad-spectrum fluoroquinolone antibiotic we are developing for the treatment of skin infections and community-acquired pneumonia, including those infections caused by methicillin-resistant staphylococcus aureus (MRSA).

MRSA has become the most frequent cause of skin and soft tissue infections being treated in emergency rooms in the United States. There are a limited number of antibiotics approved to treat MRSA, and their frequent usage has led to the emergence of multi-drug resistant bacteria. Thus, there is significant unmet medical need for new antibiotics such as JNJ-Q2 that provide flexible (oral and intravenous) treatment options for MRSA.

JNJ-Q2 was tested in a Phase II clinical trial comparing the efficacy, safety and tolerability of JNJ-Q2 with linezolid (Zyvox®) for the treatment of acute bacterial skin and skin structure infections, or ABSSSI. One hundred sixty-one patients with ABSSSI received oral treatment with either JNJ-Q2 or linezolid for 7 to 14 days. JNJ-Q2 was statistically non-inferior to linezolid for all clinical test-of-cure and short-term follow-up endpoints in the ITT population. JNJ-Q2 had a favorable safety profile and was well tolerated.

A double-blind randomized trial of patients with severe community-acquired bacterial pneumonia, or CABP, tested intravenous treatment with JNJ-Q2 versus moxifloxacin, with patients switching from intravenous to oral therapy as their conditions improved. Results are encouraging despite the fact that only 32 patients were enrolled. JNJ-Q2 provided a clinical cure rate of 87.5% versus 81.3% for patients receiving moxifloxacin. These Phase II data for CABP, together with the excellent lung penetration data demonstrated in a Phase I pharmacokinetic study, support Phase III-readiness for a CABP indication.

Furiex has a license agreement with Janssen, under which Furiex has exclusive global rights for development and commercialization of the product.

Positive Phase II Study for Skin Infections (ABSSSI) Supports Phase III Readiness

# DAYS OF TREATMENT	% OF PATIENTS CURED	
	JNJ-Q2	LINEZOLID
7 Days	44.6%	37.2%
10-14 Days	66.3%	61.5%
2-14 Days Post Rx	83.1%	82.1%

Promising clinical cure rates (traditional FDA endpoint). Success (statistical non-inferiority reached) at all clinical cure (secondary) endpoints for the ITT population.

PRILIGY®

(DAPOXETINE)

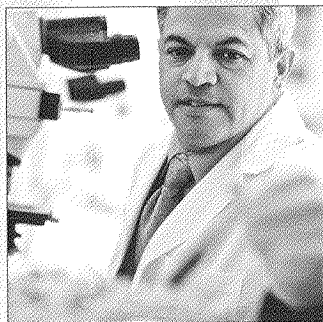
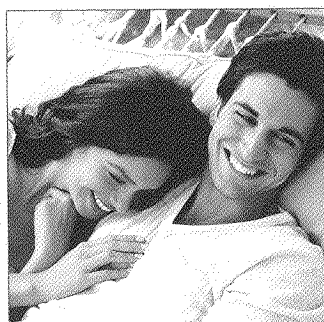
Priligy® (dapoxetine) is a drug specifically developed for the on-demand treatment of premature ejaculation and is the first oral medication to be approved for this condition.

Priligy® (dapoxetine) is a unique, short-acting, selective serotonin reuptake inhibitor, or SSRI, specifically developed for the on-demand treatment of premature ejaculation, or PE. It is the first oral medication (tablet) to be approved for this condition and is marketed by Janssen in 15 countries in Europe, Asia and Latin America. In January 2012, the European Commission recommended approval of Priligy in all E.U. member states.

Dapoxetine is designed to be taken only when needed—one to three hours before sexual intercourse—rather than every day. Dapoxetine has been extensively evaluated in five randomized, placebo-controlled Phase III clinical trials involving more than 6,000 men with PE and their partners. This is the largest and most comprehensive clinical trial program to date for a drug therapy to treat PE.

Depending on the methodology and criteria used to evaluate the prevalence of PE in studies, the reported proportion of men affected with this condition at some point in their lives has ranged from 4 to 30 percent compared to 10 to 20 percent for erectile dysfunction.

Under our drug development collaboration with Janssen we have rights to royalties and sales-based milestones from sales of Priligy.



Board of Directors



Peter Corr, Wendy Dixon, Stuart Bondurant, Fred Eshelman, Stephen Kaldor, Robert Ruscher

Fred N. Eshelman, Pharm.D.
Chairman, Furlex Pharmaceuticals, Inc.
Former Executive Chairman, PPD

Stuart Bondurant, M.D.
Emeritus Dean and Emeritus
Professor, School of Medicine,
University of North Carolina at
Chapel Hill

Peter B. Corr, Ph.D.
Co-founder and
Managing General Partner,
Celtic Therapeutics Management LLP
Retired Senior Vice President for
Science & Technology, Pfizer Inc.

Wendy L. Dixon, Ph.D.
Formerly Chief Marketing Officer and
President of Global Marketing,
Bristol-Myers Squibb

Stephen W. Kaldor, Ph.D.
President and CEO, Quantical
Venture Partner, Versant Ventures

Robert P. Ruscher
Formerly Executive Chairman,
President & CEO,
Salix Pharmaceuticals, Ltd.

Management Team



June Almenoff



Paul Covington



Gail McIntyre



Marshall Woodworth



Nadine Chien



Sailash Patel

June S. Almenoff, M.D., Ph.D.
President and Chief Medical Officer

Nadine Chien, Ph.D., Esq.
Vice President, Legal Affairs
and Secretary

Paul S. Covington, M.D.
Senior Vice President,
Clinical Development and Operations

Gail F. McIntyre, Ph.D., DABT
Senior Vice President, Research

Sailash Patel
Vice President, Strategic Development

Marshall H. Woodworth
Chief Financial Officer, Treasurer and
Assistant Secretary



Furiex[®]

2011 Form 10-K

Furiex Pharmaceuticals, Inc.

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

SEC
Mail Processing
Section

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2011

OR

APR 13 2012
Washington DC
405

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number 001-34641

FURIEX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

27-1197863
(IRS Employer
Identification No.)

**3900 Paramount Parkway, Suite 150
Morrisville, North Carolina 27560**
(Address of principal executive offices, including zip code)

(919) 456-7800
(Registrant's telephone number, including area code):

Securities registered pursuant to Section 12(b) of the Act:

(Title of each class)

(Name of each exchange on which registered)

Common Stock, par value \$0.001 per share

Nasdaq Global Market

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its Corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐ (Do not check if a smaller reporting company)

Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately \$151.0 million as of June 30, 2011, based on the closing price of the Common Stock on that date on the Nasdaq Global Market. Shares of common stock held by each executive officer and director and by each person who owns 10% or more of the outstanding common stock have been excluded in that such person might be deemed to be an affiliate. This determination of affiliate status might not be conclusive for other purposes.

As of February 29, 2012, there were 9,949,422 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The Company's definitive Proxy Statement for its 2012 Annual Meeting of Stockholders (certain parts, as indicated in Part III).

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This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements are subject to risks and uncertainties, including those set forth under “Item 1A. Risk Factors” and “Cautionary Statement” included in “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this report, that could cause actual results to differ materially from historical results or anticipated results. Unless otherwise indicated or required by the context, the terms “we,” “our,” “us” and the “Company” refer to Furiex Pharmaceuticals, Inc. and all of its subsidiaries.

PART I

Item 1. Business

Our Business

About Furiex Pharmaceuticals

We are a drug development collaboration company that uses innovative clinical development strategies to increase the value of partnered pharmaceutical assets and accelerate their development timelines. We collaborate with pharmaceutical and biotechnology companies to increase the value of their drug candidates by applying our novel approach to drug development, which we believe expedites research and development decision-making and can shorten drug development timelines. We share the risk with our collaborators by running and financing drug development programs up to agreed clinical milestones, and in exchange, we share the potential rewards, receiving milestone and royalty payments for successful drug candidates. This business model is designed to help feed product pipelines and deliver therapies to improve lives.

Our company continues the compound partnering business started by Pharmaceutical Product Development, Inc., or PPD, in 1998. We became an independent publicly traded company on June 14, 2010, when PPD spun-off its compound partnering business through a tax-free, pro-rata dividend distribution of all of the shares of the Company to PPD shareholders. PPD does not have any ownership or other form of equity interest in the Company following the spin-off. The Company's operations are headquartered in Morrisville, North Carolina. Our website address is www.furiex.com. Information on our website is not incorporated herein by reference. We make available free of charge through our website press releases, Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after electronically filed with or furnished to the Securities and Exchange Commission.

Business Description

Our goal is to in-license from or form strategic alliances with pharmaceutical and biotechnology businesses to develop and commercialize therapeutics in which the risks and rewards are shared. We seek to collaborate with pharmaceutical and biotechnology companies to increase the value of early stage drug candidates by applying our novel approach to drug development that we believe expedites research and development decision-making and can shorten drug development timelines. Furiex's team is staffed with the same key PPD team members who demonstrated proven success in the drug development collaboration business while at PPD, as well as highly-qualified additional members. Our strategy is to invest in drug candidates that have a relatively straightforward path to regulatory approval and a large addressable market. Every drug candidate we review is subjected to our rigorous due diligence process by our team of experts who possess experience in all aspects of the drug development process.

Once we in-license or form an alliance, we use our drug development experience and financial resources to advance the drug candidate through clinical development. We apply a novel approach that shortens drug development timelines that we believe transforms research and development into revenues more rapidly than the typical development cycle for such collaborations. Specifically, we set the development strategy based on a product candidate's best market position, design and manage non-clinical and clinical studies, manage the drug manufacturing programs and evaluate the efficacy and safety data necessary to obtain regulatory approvals for the drug candidate. We use service providers to execute the tasks needed to develop and commercialize our product candidates.




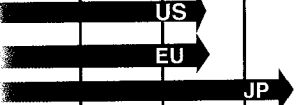
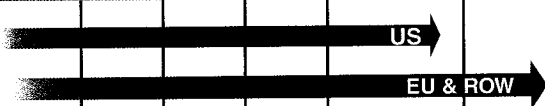


Most of our collaborations involve late development and commercialization agreements with large pharmaceutical companies. Typically, if our collaborators are unable or unwilling to execute on late stage development and commercialization, then we have the option to seek new collaborators.

In exchange for our drug development efforts and sharing the risk with our collaborator, we are entitled to receive milestone payments and royalties based on the continued development and commercialization success of the drug candidate.

Currently, we have rights to several compounds in various stages of development and commercialization, including:

- Rights to royalties and regulatory and sales-based milestone payments from Takeda Pharmaceuticals Company Limited, for alogliptin and SYR-472. Takeda received regulatory and pricing approval in Japan during the second quarter of 2010 for alogliptin for the treatment of Type-2 diabetes. Takeda markets alogliptin in Japan under the name Nesina®. In February 2011, additional indications for Nesina were approved in Japan including use in combination with two common classes of diabetes drugs, sulfonylureas and biguanides. In the third quarter of 2011, Takeda launched two dosages of Liovel®, a fixed dose combination tablet of Nesina (alogliptin) and Actos® (pioglitazone HCL), in Japan. In July 2011, Takeda announced resubmission of the U.S. NDAs for alogliptin and alogliptin in fixed-dose combination with pioglitazone. In September 2011, Takeda announced that SYR-472 entered Phase III clinical trials in Japan for treatment of Type-2 diabetes.
- Rights to royalties and regulatory and sales-based milestones from the collaboration with Alza Corporation, an affiliate of Janssen Pharmaceutica, N.V., for Priligy®, the first approved treatment in the world for premature ejaculation. Priligy is currently marketed in 15 countries in Europe, Asia-Pacific and Latin America.
- A compound licensed from Janssen, (an affiliate of Johnson & Johnson), in November 2009 that is a mu opioid receptor agonist and delta opioid receptor antagonist, which we call MuDelta, for the treatment of diarrhea-predominant irritable bowel syndrome. We completed a Phase II Proof-of-Concept clinical trial during 2011 which demonstrated that MuDelta has a favorable efficacy and safety profile. In November 2011, we acquired full exclusive license rights to develop and commercialize MuDelta under our existing development and license agreement with Janssen.
- A fluoroquinolone antibiotic licensed from Janssen in November 2009, which we call JNJ-Q2, for the treatment of acute bacterial skin and skin structure infections, such as abscesses that occur deep in the skin layers, and respiratory infections. In 2010, we completed a Phase II clinical trial using the oral formulation for acute bacterial skin infections reporting positive results. In late 2011, we halted a community-acquired bacterial pneumonia study, ongoing since late 2010, due to challenges in recruiting the study based on the current U.S. Food and Drug Administration, or FDA, guidance and recent information that the FDA's guidance may change. In April 2011, we acquired full exclusive license rights to develop and commercialize JNJ-Q2 under our existing development and license agreement with Janssen.

The following chart summarizes the status of our pipeline of compounds:

		PHASE OF DEVELOPMENT							
PROGRAM	INDICATION	Preclinical	PI	PII	PIII	Marketing Application Submission	Market	LICENSOR	COLLABORATOR¹
Royalty-based Pipeline									
Nesina®	Type 2 Diabetes							Syrrx	Takeda
Nesina/Actos® Combination	Type 2 Diabetes							Syrrx	Takeda
Nesina/ Metformin Combination	Type 2 Diabetes							Syrrx	Takeda
SYR-472	Type 2 Diabetes							Syrrx	Takeda
Priligy®	Premature Ejaculation							Eli Lilly²	Janssen
Development Pipeline									
MuDelta	IBS-diarrheal							Janssen	-
JNJ-Q2	Antibiotic							Janssen	-

¹ Refers to late-stage development and commercialization collaborator.

² Furiex originally licensed compound from Eli Lilly.

Our Solution

The drug development industry is under increasing economic pressure to develop new products more quickly and efficiently. To address this industry issue, we have developed what we believe is a novel approach to drug development. Our approach to drug development involves applying proven solutions from our extensive global drug development experience to reduce development timelines and expedite the decision-making cycle, planning for success and bridging steps in development by conducting earlier elements of a program while simultaneously planning for later phases of development.

In order to obtain regulatory approval from the FDA to market a drug, certain data about the safety and efficacy of the drug is required. To obtain such data, drug developers frequently choose to run studies sequentially. For example, they might run one study, wait to see the results, and then they run the next study. Developers prefer this approach primarily to limit upfront expenditures since the success of any given study is not known and the decision might be made not to move forward due to negative data. This sequential approach slows down the development process.

We approach drug development by minimizing the time it takes to bring products to the market. Our novel approach manages drug development with parallel processing and efficient decision-making. We use our drug development experience to predict possible outcomes of a study and take risks based on those predictions. By assuming success at each critical decision point in advance, as opposed to waiting for results, development time is reduced. In addition, we seek to mitigate risks by contingency planning for potential problems. As a result, we can accelerate the development process by bridging steps across the developmental program as well as between studies, as was evidenced with alogliptin where it took just 39 months from the filing of the Investigational New Drug application, or IND, to the filing of the New Drug Application, or NDA. Additionally, we focus our efforts on only those essential studies necessary for regulatory approval. This helps to shorten developmental timelines.

Two key elements to our approach are our due diligence process and our planning for the success of each compound. Before we enter into a collaboration for a compound, we subject it to an intense due diligence review covering every step in the development process, from preclinical and clinical studies through marketing approval. We generally look for and enter into collaborations with respect to compounds that have the following characteristics:

- address medical conditions with a significant unmet need;
- a reasonable development time;
- reasonable predictability of non-clinical models;
- clinical evidence no later than Phase Ib;
- a solid patent estate;
- acceptable estimated cost of goods; and
- attractive economic terms with the compound's innovator and ultimate commercial collaborator.

If a compound passes our rigorous diligence review hurdles, we then plan the entire development timeline upfront, using a set of assumptions. Part of the upfront planning involves initiating long-term studies, such as carcinogenicity studies, earlier than usual. We also use real-time data analysis tools to monitor the clinical study data of a drug candidate. By initiating long-term studies earlier and reviewing data in real time, we can significantly reduce the time needed after the conclusion of clinical studies to complete the necessary documentation for regulatory filing.

We believe this approach works well because the core development team is empowered to make decisions, real-time technology tools facilitate rapid data review, development programs are designed to optimize market position and timelines are driven by science and “must have” studies. The resulting ability to reduce development timelines in turn allows us to capitalize more quickly on our investment. We believe our success evolves from our development efficiency.

According to the Tufts University Center for the Study of Drug Development Outlook 2009, since 2002 the average time from the filing of an IND to the filing of an NDA is over eight years. By contrast, we advanced alogliptin as a treatment for Type-2 diabetes (for the monotherapy program) from IND to NDA in only 39 months.

Our Business Strategy

Our strategy is to in-license and develop novel early stage drug candidates that address medical conditions with a significant unmet need. We invest in innovative early stage drug candidates whose targets have scientific or clinical validation, and in disease areas that have a relatively straightforward path to regulatory approval. We leverage our extensive drug development expertise to implement efficient and high quality development

programs that accelerate time to market. We progress drug candidates to key value inflection points and form strategic collaborations with commercial pharmaceutical companies in exchange for milestones and royalties. Each potential drug candidate we consider is subjected to a rigorous review process by our due diligence team, which has expertise in all aspects of drug development, as well as in intellectual property and commercial assessment. This approach has enabled us to build what we believe is a strong, diversified portfolio of drug candidates and commercialized products that offer value to patients, our investors and collaborators. We plan to continue to grow our business by in-licensing or acquiring promising compounds and establishing new development and commercialization partnerships.

Our Portfolio

We have two Phase III-ready products in clinical development, with exclusive license rights to both products: MuDelta and JNJ-Q2. In addition we have one compound in Phase III development with a collaborator, SYR-472, and two compounds that are commercialized by collaborators, for which we are eligible to receive regulatory milestone payments plus worldwide sales royalty and milestone payments. These compounds, Nesina and Priligy, are currently marketed outside of the United States, and we have no further development obligations for any of these three compounds.

Compounds in Clinical Development

MuDelta for diarrhea-predominant irritable bowel syndrome

Diarrhea-predominant irritable bowel syndrome, or IBS-d, affects approximately 28 million patients in the United States and the five major European Union countries, and is characterized by chronic abdominal pain and frequent diarrhea. Studies have demonstrated that IBS-d is associated with work absenteeism, high medical costs and low quality of life. We believe the market for prescription treatments for IBS-d is underserved due to the limited number of available treatments and the adverse side effects associated with those treatments.

MuDelta is a novel, orally active, Phase III-ready investigational agent with combined mu opioid receptor agonist and delta opioid receptor antagonist activity. The compound's dual opioid activity is designed to treat diarrhea and pain symptoms of IBS-d, without causing the constipating side effects that occur with mu opioid agonists. MuDelta acts locally in the gut and has very low oral bioavailability, thus limiting the potential for systemic side effects, such as sedation. In January 2011, the FDA granted Fast Track designation to the MuDelta IBS-d program. Fast Track is a process for facilitating the development and expediting the review of drugs to treat serious diseases and fill unmet medical needs, with the goal of bringing important new drugs to patients earlier. Approximately 700 subjects have been treated with MuDelta to date.

In 2011, we progressed the development of MuDelta from both a developmental and regulatory perspective. We completed a large multicenter randomized-double-blind Phase II Proof-of-Concept trial in patients with IBS-d, which demonstrated that MuDelta has a favorable efficacy and safety profile. We also presented top-line data for the study at the American College of Gastroenterology 2011 meeting. Key findings from the Phase II Proof-of-Concept study results are summarized below:

The study reached statistical significance for the primary endpoint of improvement in stool consistency and abdominal pain at week four of treatment, which was developed prior to the release of the FDA's IBS guidance in 2010, as well as secondary endpoints of adequate relief of IBS-d symptoms at weeks 4, 8, and 12. Importantly, the favorable efficacy results were obtained in a *post hoc* responder analysis, using the composite endpoint of improvement in pain and diarrheal symptoms, based on the FDA 2010 guidance. Using this endpoint (where a responder is defined as a patient with a Bristol Stool Score of ≤ 4 and daily pain ratings improved by $\geq 30\%$ compared to baseline for at least 50% of days of the 12-week treatment period), MuDelta showed statistically and clinically meaningful differences compared with placebo at both the 100 mg BID and 200 mg BID doses.

The FDA agreed at our End of Phase II Meeting, that the aforementioned endpoint is an acceptable primary endpoint for Phase III pivotal studies; we believe this provides a clear regulatory path for progressing the program. We believe that our favorable Phase II study results with this endpoint bodes well for the Phase III program.

In November 2011, we acquired full exclusive license rights to develop and commercialize MuDelta under our existing development and license agreement with Janssen Pharmaceutica, N.V., or Janssen. We acquired these rights as a result of Janssen's recent decision not to exercise its option under the agreement to continue development of MuDelta. Based on our 2009 agreement, we will continue developing and commercializing the compound and Janssen may receive up to \$50.0 million in regulatory milestone payments and, if approved for marketing, up to \$75.0 million in sales-based milestone payments and sales-based royalties increasing from the mid- to upper-single digit percentages as sales volume increases. Royalties are to be paid for a period of ten years after the first commercial sale or, if later, the expiration of the last valid patent claim or the expiration of patent exclusivity.

We are actively exploring various partnering and funding options to advance development of MuDelta. In January 2012, we received favorable written feedback from the FDA on the manufacturing program, which enables us to keep program timelines on track. We are conducting Phase III manufacturing as well as other study start-up activities, with the goal of commencing Phase III dosing in the third quarter of 2012. We are also in the process of obtaining Scientific Advice from the European regulatory authorities about a European development strategy for MuDelta.

JNJ-Q2

Community-acquired bacterial pneumonia, or CABP, and acute bacterial skin and skin structure infections, or ABSSSI, are important public-health concerns due to increasing drug resistance of established antibiotics to causative pathogens. Due to the emerging resistance to established antibiotics, there is a large unmet need for antibiotics such as JNJ-Q2, that cover a broad range of pathogens, including resistant *Staphylococcus* ("Staph") and *Streptococcus* ("Strep"), and that have the potential for both intravenous and oral use. Bacterial infections are a major cause of morbidity and mortality. More than 14 million ambulatory physician visits each year are related to skin and soft-tissue infections, and approximately 94,000 Americans developed serious MRSA (methicillin resistant *Staphylococcus* "Staph" aureus) infections in 2005, according to a recent study published in the Journal of the American Medical Association. Global microbiological surveillance suggests that approximately 40% of Staph infections in the U.S., Latin America and Asia Pacific are MRSA. According to Global Data, the global MRSA market was valued at \$900 million in 2010 and is projected to exceed \$1.0 billion by 2017. The pneumonia therapeutics market was valued at \$2.0 billion in 2010 with \$1.8 billion value forecast for 2018 due to expected patent expirations.

JNJ-Q2 is a novel broad-spectrum fluoroquinolone antibiotic that also has broad coverage against two important drug resistant pathogens: MRSA and drug-resistant *Streptococcus pneumoniae*. In addition, it is highly active against other common and difficult to treat bacteria, including those that are gram-negative, gram-positive, atypical and anaerobic, and it has a low propensity for drug resistance. JNJ-Q2 is also active against resistant pathogens that might be used in bioterrorism and also, in drug-resistant gonorrhea. This broad bactericidal spectrum gives JNJ-Q2 an advantage over many other antibiotics, which do not reliably treat polymicrobial infections (i.e., wound infections containing multiple bacterial species) or such a wide variety of respiratory pathogens. We are developing JNJ-Q2 for both IV and oral use, which differentiates it from many other MRSA treatments, which are available for IV use only. The product has been in development for both skin infections and pneumonia, with the lead indication being ABSSSI.

In November 2010, we reported positive results for our randomized, double-blind, multicenter Phase II clinical trial comparing the efficacy, safety and tolerability of JNJ-Q2 with linezolid (Zyvox®) in a study of 161 patients with ABSSSI receiving oral treatment twice a day with either JNJ-Q2 or linezolid for 7 to 14 days.

JNJ-Q2 had positive results for both clinical cure and early response endpoints involving cessation of skin lesion spread or reduction in lesion size and absence of fever within 48 to 72 hours after starting treatment, consistent with the latest FDA draft guidance, with a slightly higher response rate for JNJ-Q2 at 62.7% than for linezolid at 57.7%. These results were published in the December 2011 issue of Antimicrobial Agents and Chemotherapy (Volume 55: pages 5790-5797) and are also available on line <http://aac.asm.org/content/55/12/5790.full>.

In April 2011, we acquired full exclusive license rights to develop and commercialize JNJ-Q2 under our existing development and license agreement with Janssen. We acquired rights to JNJ-Q2 as a result of Janssen's decision not to exercise its option under the agreement which gave Janssen the opportunity to continue development of JNJ-Q2. This decision was related to Janssen's April 2011 announcement that it will be directing its research and development investments toward antivirals and vaccines and would not be investing in new antibacterial therapies. Based on our existing agreement, Janssen may receive up to \$50.0 million in regulatory milestone payments, and if approved for marketing, up to \$75.0 million in sales-based milestone payments and sales-based royalties increasing from the mid- to upper-single digit percentages as sales volume increases. Royalties would be paid for a period of ten years after the first commercial sale or, if later, the expiration of the last valid patent claim or the expiration of patent exclusivity.

In June and July of 2011, we had productive End of Phase II meetings with both the FDA and with several EU regulatory authorities, providing what we believe is a clear regulatory path to support global Phase III development in ABSSSI. Also, a total of 13 peer-reviewed scientific papers and abstracts on JNJ-Q2 were published in 2011.

In the fourth quarter of 2011, we terminated our study of community-acquired bacterial pneumonia prior to full recruitment. This decision was made for business reasons related to challenges in recruiting the study based on the current FDA guidance and recent information that the FDA's guidance might change. The study was a double-blind randomized trial where patients with severe community-acquired pneumonia received intravenous treatment with JNJ-Q2 (twice daily) versus moxifloxacin (once daily), and were switched from IV to oral therapy as their conditions improved. Although we enrolled only 32 patients, the data from this small study gives us valuable qualitative information about the drug's efficacy and tolerability in this very ill patient population. The results were encouraging, with a clinical cure rate (primary endpoint) of 87.5% for patients receiving JNJ-Q2 versus 81.3% of patients receiving moxifloxacin. The study was too small, however, to verify statistical significance (i.e., non-inferiority testing). For the secondary endpoint of clinical stability at day 4 (determined by patients' vital signs and respiratory status) 50.0% of patients receiving JNJ-Q2 met the endpoint compared with 43.8% of patients receiving moxifloxacin. Both the IV and oral formulations of JNJ-Q2 had favorable tolerability and safety profiles, with no nausea or vomiting reported.

We believe that these Phase II clinical trial data for CABP, taken together with the excellent lung penetration data from our Phase I study, support Phase III-readiness for a CABP indication. We believe these data add value to the asset, in that the Phase III-readiness of JNJ-Q2 for two indications may provide a competitive advantage over other antibiotics in the development pipeline.

We indicated in the fourth quarter of 2011 that we were invited to submit a government contract proposal for research funding of JNJ-Q2 to the Biomedical Advanced Research and Development Authority, or BARDA. Although we had a productive pre-proposal meeting with BARDA, we have elected not to proceed with a contract proposal at present, because of limitations in government funding to support Phase III development.

We are continuing to seek to out-license JNJ-Q2. We plan to maintain the Phase III-readiness of the program, which should require minimal expenditures during 2012. We believe this drug has the potential to be valuable broad spectrum therapy for serious skin and lung infections.

PPD-10558 (Statin compound)

In December 2006, we entered into an exclusive license agreement with Ranbaxy Laboratories, Ltd., or Ranbaxy, for rights to PPD-10558 as a potential treatment for dyslipidemia, a condition characterized by high cholesterol. In December 2011, we announced top-line results from the Phase II trial of the investigational drug PPD-10558 in patients with a history of statin-associated myalgia, or SAM. PPD-10558 did not meet its primary efficacy endpoint in this study.

Based on these results, we have made a decision to discontinue further spending on the PPD-10558 program and plan to terminate our license agreement with Ranbaxy in accordance with the terms of the agreement. As part of the agreement, we will owe Ranbaxy a \$1.0 million development milestone payment upon completion of the Phase II final study report, which we anticipate will occur in the second quarter of 2012.

Marketed Products

Nesina (alogliptin) for Type II diabetes

Globally, as of 2010, it is estimated that there are 285 million people with diabetes. Type-2 diabetes comprises about 85%-95% of the total cases of diabetes. Worldwide sales of anti-diabetic treatments in 2010 were \$34.4 billion.

Nesina, which is marketed by Takeda Pharmaceuticals Company Limited, or Takeda, is the trade name for alogliptin, a member of a relatively new class of drugs for the oral treatment of Type-2 diabetes. Nesina is a highly selective dipeptidyl peptidase-4, or DPP-4, inhibitor that slows the inactivation of hormones known as incretins, which play a major role in regulating blood sugar levels and might improve pancreatic function. Pivotal trials demonstrated that Nesina was well-tolerated when given as a single daily dose and it significantly improved glycemic control in Type-2 diabetes patients without raising the incidence of hypoglycemia. Additionally, Nesina has been shown to enhance glycemic control when used in combination with other commonly prescribed diabetes drugs.

We continue to see increasing sales of Nesina in Japan, with royalty revenues growing more than 64% over each of the last two quarters. Nesina was approved in Japan as monotherapy for Type-2 diabetes in 2010. In February 2011, additional indications for Nesina were approved in Japan for use in combination with sulfonylureas and use in combination with biguanides. In the third quarter of 2011, Takeda launched two dosages of Liovel, a fixed dose combination tablet of Nesina (alogliptin) and Actos (pioglitazone HCL), in Japan.

In July 2011, Takeda announced resubmission of the U.S. NDAs for alogliptin and alogliptin in fixed-dose combination with pioglitazone and a Prescription Drug User Fee Act, or PDUFA, action date of January 25, 2012 was assigned by the FDA. On November 18, 2011, Takeda announced that the PDUFA action date was delayed until April 25, 2012. If U.S. approval is granted, we would be eligible to receive a \$25.0 million milestone payment as well as royalties and sales-based milestones. Also, Takeda announced that it had submitted an NDA in the U.S. for a fixed-dose combination of alogliptin and metformin, and that this application has a PDUFA action date in December 2012.

SYR-472 is part of the DPP-4 inhibitor portfolio that Takeda purchased from PPD and Syrrx in 2005. SYR-472 has the same mechanism of action as alogliptin. However, in contrast to alogliptin, which is a once-daily oral therapy, SYR-472 is a once-weekly oral formulation, which offers potential for greater convenience for diabetes patients. On September 8, 2011, Takeda announced that SYR-472 entered Phase III clinical trials in Japan for treatment of Type-2 diabetes. If SYR-472 is approved, then we would be eligible to receive royalty payments at the same rates as for Nesina. Under our agreement with Takeda, we would be entitled to receive milestone payments for SYR-472 or Nesina, whichever compound achieves the milestone(s) first.

Under our agreement with Takeda, we will be entitled to receive up to \$45.0 million in future regulatory milestone payments (\$25.0 million for U.S. approval, \$10.0 million on regulatory filing for marketing authorization in the EU and \$10.0 million for EU marketing authorization), and up to \$33.0 million in sales-based milestone payments. In addition, we are entitled to receive payments on worldwide sales of Nesina based on royalty rates of 7% to 12% in the U.S., 4% to 8% in Europe and Japan and 3% to 7% in regions other than the U.S., Europe or Japan. These royalty payments are subject to a reduction of up to 0.5% for a portion of payments by Takeda to a licensor for intellectual property related to Nesina. Royalties are to be paid for the later of ten years following the first commercial sale or two years following the expiration of the last to expire patent. Takeda must pay us royalties for Liovel sales based on the proportion of Nesina's average sales price compared to that of pioglitazone plus Nesina. We have no further financial obligation under this agreement.

Priligy (dapoxetine) for premature ejaculation

Priligy is the trade name for dapoxetine, a drug in tablet form specifically indicated for the "on-demand" treatment of premature ejaculation, or PE. It is the first oral medication to be approved for this condition. The reported percentage of men affected with PE at some point during their lives ranges from 4% to 30%, depending on the methodology and criteria used. Priligy is a unique, short-acting, selective serotonin reuptake inhibitor, or SSRI, designed to be taken only when needed, one to three hours before sexual intercourse, rather than every day. Priligy has been studied in five randomized, placebo-controlled Phase III clinical trials involving more than 6,000 men with PE and is marketed in 15 countries in Europe, Asia-Pacific and Latin America. Additional clinical studies are being conducted on Priligy in the U.S. and abroad. We are enthusiastic about the potential for Priligy ex-U.S.; however, we cannot assure that the drug will be approved in the United States.

We are actively evaluating and pursuing the possibility of restructuring the existing agreement with Alza Corporation, or Alza, for Priligy, with the possibility of involving another collaborative partner. Any transaction might require that the Company negotiate additional out-licenses or collaborations, and could require additional external sources of financing.

We acquired Priligy from Eli Lilly and Company, or Lilly, and out-licensed it to Alza, and it is currently being marketed by Alza's affiliate Janssen. Under our license agreement with Alza, we have the right to receive up to \$15.0 million in additional regulatory milestone payments, up to \$50.0 million in sales-based milestone payments, and sales-based royalties ranging from 10% to 20% for sales of patented products without generic competition and ranging from 10% to 17.5% for non-patented products without generic competition, in both cases the percentages rise as sales volumes increase, and a royalty of 7.5% for patented and non-patented products with generic competition regardless of sales volume based on the level of Priligy sales worldwide. We are obligated to pay Lilly a royalty of 5% on annual sales in excess of \$800.0 million.

Priligy has been marketed in seven European countries since 2009: Germany, Spain, Italy, Portugal, Finland, Sweden and Austria. In January 2012, the European Commission endorsed the positive opinion adopted by the Committee for Human Medicinal Products for Priligy (dapoxetine) 30 mg and 60 mg doses. Pending national approvals, the marketing authorization for the Priligy doses can be granted in the 20 European Union Member States where the drug has not yet been approved (including the United Kingdom and France), as well as in Norway and Iceland.

Our Drug Development Capabilities

The drug development capabilities of our executive officer team embodies over 50 years of research and development experience. This experience includes a deep understanding of the biological causes of human diseases and the factors that impact all aspects of successful drug development such as manufacturing, formulation, the cause of drug side effects, drug interactions and drug pharmacokinetics. We believe that our drug development capability and proven success rate will continue to provide a pipeline of unique compounds. Depending upon the availability of our development resources, our preclinical candidates might be added to our own internal clinical pipeline, or out-licensed to other companies for clinical development and commercialization.

Our Patents and Other Proprietary Rights

Patents and other proprietary rights are important to our business. It is our policy to seek patent protection for our assets, and also to rely upon trade secrets, know-how and licensing opportunities to develop and maintain our competitive position.

We own or have exclusively licensed 15 issued U.S. patents and have approximately 290 U.S. and non-U.S. pending patent applications. We have a policy to seek worldwide patent protection for our products and have foreign patent rights corresponding to most of our U.S. patents.

We license the rights to the following material patents related to our product candidates:

- MuDelta. Licensed from Janssen. The license continues as long as we meet our obligations to Janssen and we have marketing rights to the compound. As of December 31, 2011, 23 U.S. and foreign patents have been issued to Janssen in this patent family. Additional U.S. and foreign patent applications are still pending.
- JNJ-Q2. Licensed from Janssen. The license continues as long as we meet our obligations to Janssen and we have marketing rights to the compound. As of December 31, 2011, 56 U.S. and foreign patents have been issued to Janssen in this patent family. Additional U.S. and foreign patent applications are still pending.

Pursuant to the terms of the Uruguay Round Agreements Act, patents issued from applications filed on or after June 8, 1995, have a term of 20 years from the date of filing, no matter how long it takes for the patent to issue. Because patent applications in the pharmaceutical industry often take a long time to issue, this method of patent term calculation can result in a shorter period of patent protection afforded to us compared to the prior method of term calculation, which was 17 years from the date of issue. Our issued U.S. patents expire between 2023 and 2029, excluding any potential patent term extension available under U.S. federal law. We actively seek full patent term adjustment following allowance of a patent. We also actively seek patent term extensions following marketing approval. Under the Drug Price Competition and Patent Term Restoration Act of 1984 and the Generic Animal Drug and Patent Term Restoration Act of 1988, a patent that claims a product, use or method of manufacture covering drugs may be extended for up to five years to compensate the patent holder for a portion of the time required for FDA review.

While we file and prosecute patent applications to protect our inventions, our pending patent applications might not result in the issuance of patents or our issued patents might not provide competitive advantages. Also, our patent protection might not prevent others from developing competitive products using related or other technology.

In addition to seeking the protection of patents and licenses, we also rely upon trade secrets, know-how and continuing technological innovation, which we seek to protect, in part, by confidentiality agreements with employees, consultants, suppliers and licensees.

The scope, enforceability and effective term of issued patents can be highly uncertain and often involve complex legal and factual questions. No consistent policy has emerged regarding the breadth of claims in pharmaceutical patents, so that even issued patents might later be modified or revoked by the relevant patent authorities or courts. Moreover, the issuance of a patent in one country does not assure the issuance of a patent with similar claim scope in another country, and claim interpretation and infringement laws vary among countries, so we are unable to predict the extent of patent protection in any country. The patents we obtain and the unpatented proprietary technology we hold might not afford us significant commercial protection. Additional information regarding risks associated with our patents and other proprietary rights that affect our business is contained under the headings “We must protect our patents and other intellectual property rights to succeed” and “We might need to obtain patent licenses from others in order to manufacture or sell our potential products and we might not be able to obtain these licenses on terms acceptable to us or at all” under the heading “Risk Factors”.

Manufacturing and Supply

We currently rely on our collaborators and contract manufacturers to produce drug substances and drug products required for our clinical trials under current good manufacturing practices, with oversight by our internal managers. We plan to continue to rely upon contract manufacturers and collaboration partners to manufacture commercial quantities of our drug candidates if and when approved for marketing by the applicable regulatory agency. We generally rely on one manufacturer for the active pharmaceutical ingredient and another manufacturer for the formulated drug product for each of our drug candidate programs. At the early stage of clinical studies, we do not believe that we are substantially dependent on any supplier, or that additional manufacturers would be beneficial due the possibility of changes in the method of manufacturing of the drug candidate. As a drug candidate moves to later stages of development and the drug formulation method is established, we then seek additional manufacturers for the drug.

Sales and Marketing

We currently have no marketing, sales or distribution capabilities. We plan to rely on third party collaborators to market our products, like Alza for Priligy and Takeda for Nesina and related products, and therefore we are subject to the strategic marketing decisions of such third parties. We generally plan to out-license our commercial rights in a territory to a third party with marketing, sales and distribution capabilities in exchange for one or more of the following: up-front payments; research funding; development funding; milestone payments; and royalties on drug sales. In some instances, however, we might choose to develop our own staff for marketing, sales or distribution.

Government Regulation

The manufacturing, testing, labeling, approval and storage of our products are subject to rigorous regulation by numerous governmental authorities in the United States and other countries at the federal, state and local level, including the FDA. The process of obtaining approval for a new pharmaceutical product or for additional therapeutic indications within this regulatory framework requires expenditure of substantial resources and usually takes several years. Companies in the pharmaceutical and biotechnology industries, including us, have suffered significant setbacks in various stages of clinical trials, even in advanced clinical trials after promising results had been obtained in earlier trials.

The process for obtaining FDA approval of drug candidates customarily begins with the filing of an IND with the FDA for the use of a drug candidate to treat a particular indication. If the IND is accepted by the FDA, we would then start human clinical trials to determine, among other things, the proper dose, safety and efficacy of the drug candidate in the stated indication. The clinical trial process is customarily divided into three phases—Phase I, Phase II and Phase III. Each successive phase is generally larger and more time-consuming and expensive than the preceding phase. Throughout each phase we are subject to extensive regulation and oversight by the FDA. Even after a drug is approved and being marketed for commercial use, the FDA may require that we conduct additional trials, including Phase IV trials, to further study safety or efficacy.

As part of the regulatory approval process, we must demonstrate to the FDA the ability to manufacture a pharmaceutical product before we receive marketing approval. We and our manufacturing collaborators must conform to rigorous standards regarding manufacturing and quality control procedures in order to receive FDA approval. The validation of these procedures is a costly endeavor. Pharmaceutical manufacturers are subject to inspections by the FDA and local authorities as well as inspections by authorities of other countries. To supply pharmaceutical products for use in the United States, foreign manufacturers must comply with these FDA-approved guidelines. These foreign manufacturers are also subject to periodic inspection by the FDA or by corresponding regulatory agencies in these countries under reciprocal agreements with the FDA. Moreover, state, local and other authorities may also regulate pharmaceutical product manufacturing facilities. Before we are able to manufacture commercial products, we or our contract manufacturer, as the case may be, must meet FDA guidelines.

Both before and after marketing approval is obtained, a pharmaceutical product, its manufacturer and the holder of the Biologics License Application, or BLA, or NDA for the pharmaceutical product are subject to comprehensive regulatory oversight. The FDA may deny approval to a BLA or NDA if applicable regulatory criteria are not satisfied. Moreover, even if regulatory approval is granted, such approval may be subject to limitations on the indicated uses for which we may market the pharmaceutical product. Further, marketing approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems with the pharmaceutical product occur following approval. In addition, under a BLA or NDA, the manufacturer of the product continues to be subject to facility inspections and the applicant must assume responsibility for compliance with applicable pharmaceutical product and establishment standards. Violations of regulatory requirements at any stage may result in various adverse consequences, which may include, among other adverse actions, withdrawal of the previously approved pharmaceutical product or marketing approvals or the imposition of criminal penalties against the manufacturer or BLA or NDA holder.

For the development of pharmaceutical products outside the United States, we and our collaborators are subject to foreign regulatory requirements and the ability to market a drug is contingent upon receiving marketing authorizations from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials and marketing authorization vary widely from country to country. In countries other than European Union countries, foreign marketing authorizations are applied for at a national level. Within the European Union, procedures are available to companies wishing to market a product in more than one European Union member state. Clinical trial applications must be filed with the relevant regulatory authority in each country in which we would want to conduct a clinical trial. Assuming approval and the success of any clinical trial, we would then need to seek marketing approval for the drug. The process for obtaining marketing approval of drug candidates in the European Union begins with the filing with the European Medicines Agency, or EMA, of a Marketing Authorization Application, or MAA, for the use of a drug candidate to treat a particular indication. Similar processes and outcomes of such human clinical trials that are required by the FDA are also required by the EMA including testing for dose, safety and efficacy in three phases. Similar to the FDA, we are subject to extensive regulation and oversight by the European regulators throughout each phase. Even after a drug is approved and being marketed for commercial use, the EMA may require that we conduct additional trials, including Phase IV trials, to further study safety or efficacy. As a result, the EMA regulatory approval process includes all of the risks associated with FDA approval set forth above.

If and when necessary, we will choose the appropriate route of European or other international regulatory filing to accomplish the most rapid regulatory approvals. Requirements relating to manufacturing, conduct of clinical trials and product licensing vary widely in different countries, and the chosen regulatory strategy might not secure regulatory approvals or approvals of our chosen product indications. In addition, if a particular product to be used outside of the United States is manufactured in the United States, FDA requirements and U.S. export provisions will apply.

Outside of the United States, many countries require us to obtain pricing approval in addition to regulatory approval prior to launching the product in the approving country. We or our licensees may encounter difficulties or unanticipated costs or price controls in our respective efforts to secure necessary governmental approvals. Failure to obtain pricing approval in a timely manner or approval of pricing which would support an adequate return on investment or generate a sufficient margin to justify the economic risk might delay or prohibit the commercial launch of the product in those countries.

The marketing and sale of approved pharmaceutical product is subject to strict regulation. Promotional materials and activities must comply with the approving agency's regulations and other guidelines. Physicians may prescribe pharmaceutical or biologic products for uses that are not described in a product's labeling or differ from those approved by the approving agency. While such "off-label" uses are common and regulatory agencies do not regulate physicians' choice of treatments, many approving agencies restrict a company's communications on the subject of "off-label" use. Companies cannot promote approved pharmaceutical or biologic products for off-label uses. If any advertising or promotional activities we undertake fail to comply with applicable regulations or guidelines regarding "off-label" use, we may be subject to warnings or enforcement action.

Competition

The pharmaceutical industry is highly competitive. Many of our competitors are worldwide conglomerates with substantially greater resources than we have to develop and commercialize their drugs and drug candidates. Potential competitors have developed and are developing compounds for treating the same indications as our product candidates. In addition, a number of academic and commercial organizations are actively pursuing similar technologies, and several companies have developed or may develop technologies that might compete with our compounds.

Priligy, indicated for premature ejaculation, competes with Cromadyn, a generic paroxetine sold by More Pharmaceuticals in Mexico. Additional competition includes “off label” treatment with chronically dosed SSRIs (e.g. paroxetine, fluoxetine). We are aware of three other compounds in development for premature ejaculation: (1) PD502 (Phase III) novel formulation of lidocaine and prilocaine being developed by Shionogi that is administered topically (2) Zertane (Phase III) a re-purposed formulation of tramadol (a centrally acting oral opioid mu receptor agonist with serotonin and norepinephrine reuptake inhibitory activities), being developed ex-U.S. by Ampio Pharma, and (3) GSK-557296 (Phase II) an oxytocin receptor antagonist, being developed by GlaxoSmithKline.

Nesina competes in the Type-2 diabetes space with three DPP4 inhibitors currently on the market, Bristol-Myers Squibb/AstraZeneca’s Onglyza® (saxagliptin), Boehringer Ingelheim/Lilly’s Tradjenta™ (linagliptin) and Merck’s Januvia® (sitagliptin). Merck also markets Janumet®, a fixed-dose combination of sitagliptin and metformin, Boehringer Ingelheim/Lilly, Jentadueto™, a combination of linagliptin and metformin, and Bristol-Myers Squibb/AstraZeneca, Kombiglyze®, a combination of saxagliptin and extended release metformin. Novartis markets the DPP4 inhibitor Galvus® (vildagliptin) and Eucreas® (vildagliptin/metformin) in Europe. Other marketed oral anti-diabetic competitors include generic metformin, generic sulfonylureas, and thiazolidinediones, including GlaxoSmithKline’s Avandia® (rosiglitazone) and Takeda’s Actos (pioglitazone). Generic competitors to Avandia and Actos are expected to enter the market in 2012.

The diabetes pipeline is crowded, with, to our knowledge, approximately 90 compounds in Phase I development, approximately 80 in Phase II development, and approximately 25 in Phase III development or preregistration. In addition to DPP4 inhibitors, competitors are also developing GLP-1 agonists, SGLT-2 antagonists, PPAR agonists, and compounds with other mechanisms for treatment of diabetes. Other companies with DPP4 inhibitors in clinical development of which we are aware include Amgen/Servier, Arisaph Pharmaceuticals, Dong-A Pharmaceuticals (South Korea), Dainippon Sumitomo Pharma, Phenomix, Glenmark Pharmaceuticals, Kyorin Pharmaceuticals, LG Life Sciences (South Korea), Mitsubishi Tanabe Pharma, and Sanwa Kagaku Kenkyusho (Japan).

If approved, JNJ-Q2 will compete with other fluoroquinolones currently on the market, including Johnson and Johnson’s Levaquin® (levofloxacin), Bayer/Merck’s Avelox® (moxifloxacin), Bayer/Merck’s Cipro® (ciprofloxacin), and Cornerstone Therapeutics’s Factive® (gemifloxacin). Generic versions of ciprofloxacin and levofloxacin are currently available, and generic versions of moxifloxacin will likely become available when the patents covering these products expire in 2014. If JNJ-Q2 is found to be effective against MRSA infections, it would compete with Pfizer’s Zyrox® (linezolid), Cubist’s Cubicin (daptomycin), Wyeth’s Tygacil (tigecycline), Theravance’s Vibativ® (telavancin), Forest’s Teflo™ (ceftaroline), and the generic drug vancomycin.

Companies developing compounds to treat MRSA infections in clinical trials include Baselia, Nabriva, Trius, Paratek/Novartis, Cempira, Durata, Affinium, e-Therapeutics, FAB Pharma, Medicines Company, Novoxel (now AstraZeneca), Phico Therapeutics, PolyMedix, Rib-X Pharmaceuticals, TaiGen, Theravance, and Wockhardt (India). The Rib-X and Wockhardt compounds are both fluoroquinolones. In addition, MerLion Pharmaceuticals is developing a fluoroquinolone in Phase II. Merck and Nabi Biopharmaceuticals are both developing vaccines against staphylococcus aureus.

If approved, MuDelta will compete with Lotronex® (alosetron), marketed by Prometheus Laboratories. Generic opiates and/or antispasmodic agents are also used for diarrhea predominant IBS: loperamide (Imodium®, an over the counter anti-diarrheal), diphenoxylate/atropine (an opiate/anticholinergic agent), and dicyclomine. The pipeline for diarrhea-predominant IBS includes: asimadoline, which is being developed by Tioga Pharmaceuticals and is in Phase III, rifaximin, an antibiotic approved product for hepatic encephalopathy that is the subject of a supplemental NDA, by Salix Pharmaceuticals; AST-120, currently in Phase II development by Ocera; ibodutant (NK 2 antagonist), currently in Phase II development by Menarini Group; ramosetron (a 5HT3 antagonist), currently in Phase II development by Astellas Pharma; dextofisopam, currently in Phase II development by Pharmos Corporation; and LX1031 (a serotonin synthesis inhibitor), currently in Phase II development by Lexicon Pharmaceuticals.

Competitors might succeed in more rapidly developing and marketing technologies and products that are more effective than our products or that would render our products or technology obsolete or noncompetitive. Our collaborators might also independently develop products that are competitive with products that we have licensed to them. Any product that we or our collaborators succeed in developing and for which regulatory approval is obtained must then compete for market acceptance and market share. The relative speed with which we and our collaborators can develop products, complete clinical testing and approval processes, and supply commercial quantities of the products to the market compared to competitive companies will affect market success. In addition, the amount of marketing and sales resources, and the effectiveness of the marketing used with respect to a product will affect its success. In addition, some clinical research organizations, or CRO, service providers and private equity funds are developing risk sharing models to finance the pharmaceutical industry's pipeline. NovaQuest, a subsidiary of Quintiles Transnational, is active in this business. As these types of business models evolve, there will be increasing competition for compounds and funds that will affect our ability to add to our portfolio.

Other competitive factors affecting our business generally include:

- product efficacy and safety;
- timing and scope of regulatory approval;
- product availability, marketing and sales capabilities;
- reimbursement coverage;
- the amount of clinical benefit of our product candidates relative to their cost;
- method of and frequency of administration of any of our product candidates which may be commercialized;
- patent protection of our product candidates;
- the capabilities of our collaborators; and
- the ability to hire qualified personnel.

Employees

We have 24 full-time employees, a majority of whom are engaged in research and development activities. Our success depends in large part on our ability to attract and retain skilled and experienced employees. None of our employees are covered by a collective bargaining agreement. We consider our relations with our employees to be good.

Item 1A. Risk Factors

Our business operations face a number of risks. These risks should be read and considered with other information provided in this report.

Risks Relating to Furiex's Business

We anticipate that we will incur additional losses. We might never achieve or sustain profitability. If additional capital is not available, we might have to curtail or cease operations.

Our business has experienced significant net losses. We had net losses of \$8.9 million, \$54.7 million and \$49.0 million in 2009, 2010 and 2011, respectively. The results for 2009 and 2010 included aggregate milestone payments of \$5.0 million and \$7.5 million, respectively. We did not receive any milestone payments during 2011. We will continue to incur additional net losses, as we continue our research and development activities and incur significant preclinical and clinical development costs, until revenues from all sources reach a level sufficient to support our ongoing operations. Because we or our collaborators or licensees might not successfully develop additional products, obtain required regulatory approvals, manufacture products at an acceptable cost or with appropriate quality, or successfully market products with desired margins, our expenses might continue to exceed any revenues we receive. Our commitment of resources to the continued development of our products might require significant additional funds for development. Our operating expenses also might increase if we:

- move our earlier stage potential products into later stage clinical development, which is generally a more expensive stage of development;
- encounter problems during clinical development that require a change in scope and/or timelines resulting in higher costs;
- pursue clinical development of our potential products in new indications;
- increase the number of patents we are prosecuting or otherwise expend additional resources on patent prosecution or defense;
- invest in or acquire additional technologies, product candidates or businesses, although we have no current agreements to do so; or
- impair any of our investments in our product candidates.

In the absence of substantial licensing, milestone and other revenues from third-party collaborators, royalties on sales of products licensed under our intellectual property rights, future revenues from our products in development or other sources of revenues, we will continue to incur operating losses and might require additional capital to fully execute our business strategy. The likelihood of reaching, and time required to reach, sustained profitability are highly uncertain.

Although we expect that we will have sufficient cash to fund our operations and working capital requirements for at least the next 12 months based on current operating plans, we might need to raise additional capital in the future to:

- fund our research and development programs;
- acquire complementary businesses or technologies;
- respond to competitive pressures; or
- commercialize our product candidates.

Our future capital needs depend on many factors, including:

- the scope, duration and expenditures associated with our research and development programs;

- continued scientific progress in these programs;
- the outcome of potential licensing transactions, if any;
- competing technological developments;
- our proprietary patent position, if any, in our product candidates;
- the regulatory approval process for our product candidates; and
- the cost of attracting and retaining employees.

We might seek to raise necessary funds through public or private equity offerings, debt financings or additional collaborations and licensing arrangements. We might not be able to obtain additional financing on terms favorable to us, if at all. General market conditions might make it difficult for us to seek financing from the capital markets. We might have to relinquish rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us, in order to raise additional funds through collaborations or licensing arrangements. If adequate funds are not available, we might have to delay, reduce or eliminate one or more of our research or development programs and reduce overhead expenses, or restructure or cease operations. These actions might reduce the market price of our common stock.

Our near-term revenue is largely dependent on the success of Nesina and Priligy as well as our other drug candidates, and we cannot be certain that our collaborators will be able to obtain regulatory approval for or commercialize any of these drug candidates.

We currently are relying on Nesina and Priligy to generate revenue. While Priligy is approved for marketing outside of the U.S., it has not been approved in the U.S. and the FDA issued a not approvable letter to our collaborative partner at the time, Janssen, in October 2005. We are investigating regulatory strategies for a potential refiling with the FDA. While Nesina is approved for marketing in Japan, Takeda, our collaborative partner, continues to seek approval in the U.S. and Europe. Takeda is performing a cardiovascular safety trial for alogliptin and has refiled its NDA with the FDA. A decision by the FDA is expected in the second quarter of 2012. The data from this cardiovascular safety trial might also impact the approval of Nesina by the EMA. We have also invested a significant amount of time and financial resources in the development of JNJ-Q2. FDA guidance for developing drugs to treat community-acquired bacterial pneumonia includes challenging requirements for the drug developer. Our future success might depend on our collaborator's ability to successfully complete the Phase III trial for this pneumonia indication using JNJ-Q2 in view of the FDA guidelines. We have also invested a significant amount of time and financial resources in the development of MuDelta. Our future success might depend on our or our collaborator's ability to successfully complete Phase III clinical trials for MuDelta. We anticipate that our success will depend largely on the receipt of regulatory approval and successful commercialization of these drug candidates. The future success of these drug candidates will depend on several factors, including the following:

- our ability to provide acceptable evidence of their safety and efficacy;
- receipt of marketing approval from the FDA and any similar foreign regulatory authorities;
- obtaining and maintaining commercial manufacturing arrangements with third-party manufacturers or establishing commercial-scale manufacturing capabilities;
- collaborating with pharmaceutical companies or contract sales organizations to further develop, market and sell any approved drug;
- acceptance of any approved drug in the medical community and by patients and third-party payors; and
- successful review of the alogliptin NDA by the FDA leading to a marketing authorization.

Many of these factors are beyond our control. Accordingly, we cannot assure you that we will be able to continue generating revenues through the sale of Priligy or Nesina or generate any revenue from the sale of other product candidates.

Our ability to continue to develop and commercialize our late stage product candidates depends on our ability to find new collaborators.

Our ability to succeed in our drug development business by advancing our late stage product candidates through Phase III clinical trials will depend on our ability to successfully find collaborators able to fund and execute late-stage development and commercialization of our product candidates. We generally conduct our drug development business in two stages. During the first stage, we in-license a product candidate from a collaborator and develop that candidate through Phase II clinical trials. If the product candidate successfully completes Phase II testing, we enter a second stage during which we seek a collaborator, which might be the same collaborator as in the first stage, for the continued late stage development and ultimate commercialization of the product candidate. Janssen, our original collaborator for JNJ-Q2 and MuDelta, has elected not to continue development of these two product candidates. If we cannot find a collaborator for final development and commercialization, we might not be able to complete the development and commercialization on our own due to the significant costs associated with these activities. As a result, we may not be able to recoup all or any part of our investment in the product candidate.

Our milestone and royalty payments from collaborators and the successful development and marketing of our product candidates depends on our collaborators continuing to develop and commercialize the product candidates. If our collaborators are not successful or choose not to develop these compounds, we might not receive future payment.

The drug development industry is under increasing economic pressure. The third parties with which we collaborate might not perform their obligations as expected or they might breach or terminate their agreements with us or otherwise fail to conduct their collaborative activities successfully or in a timely manner. Further, parties collaborating with us who elect to develop a drug candidate might not devote sufficient resources to the development, manufacture, regulatory strategy and approvals, marketing or sale of these product candidates. If the parties to our collaborative agreements do not fulfill their obligations, elect not to develop a candidate or fail to devote sufficient resources to it, our business could be materially and adversely affected. In these circumstances, our ability to further develop potential products could be severely limited. While we generally seek non-compete terms in our agreements with our collaborators for the products we are developing, the enforcement of a non-compete can be expensive and difficult to monitor and enforce and might be subject to being invalidated by a court or judge.

We have agreements under which we rely on collaborators to manufacture our product candidates and essential components for those product candidates, design and conduct clinical trials, compile and analyze the data received from these trials, obtain regulatory approvals and, if approved, market these products. As a result, we may have limited or no control over the manufacturing, development and marketing of these potential products. In addition, the performance of our collaborators might not be sufficient or appropriate for regulatory review and approval for our product candidates. Further, we often rely on one manufacturer or other collaborator for such services, the loss of which could significantly delay the development of any of our product candidates. Our milestone and royalty payments rely on the performance of our collaborators and would be impacted by any delay or termination by our collaborators.

Our collaborators can terminate our collaborative agreements under certain conditions. A collaborator may terminate its agreement with us or separately pursue alternative products, therapeutic approaches or technologies as a means of developing treatments for the diseases targeted by us, or our collaborative effort. Even if a collaborator continues to contribute to the arrangement, it might nevertheless decide not to actively pursue the development or commercialization of any resulting products. In these circumstances, our ability to further

develop potential products could be severely limited. While we generally seek non-compete terms in our agreements with our collaborators for the products we are developing, the enforcement of a non-compete can be expensive and difficult to monitor and enforce and might be subject to being invalidated by a court or judge.

Continued funding and participation by collaborators will depend on the continued timely achievement of our research and development objectives, the retention of key personnel performing work under those agreements and on each collaborator's own financial, competitive, marketing and strategic capabilities and priorities. These considerations include:

- the commitment of each collaborator's management to the continued development of the licensed products or technology;
- the relationships among the individuals responsible for the implementation and maintenance of the development efforts; and
- the relative advantages of alternative products or technology being marketed or developed by each collaborator or by others, including their relative patent and proprietary technology positions, and their ability to manufacture potential products successfully.

The willingness of our existing collaborators to continue development of our potential products and our ability to enter into new relationships depends upon, among other things, our patent position with respect to such products. If we are unable to successfully obtain and maintain patents, we might be unable to collect royalties on existing licensed products or enter into additional agreements.

In addition, our collaborators might independently develop products that are competitive with products that we have licensed to them. This could reduce our revenues or the likelihood of achieving revenues under our agreements with these collaborators.

If we are unable to enter into agreements with third parties to market and sell our drug candidates or are unable to establish our own sales and marketing capabilities, we might be unable to generate product revenue.

We do not currently have the resources to sell, market or distribute any pharmaceutical products. In order to market any of our products that receive regulatory approval, we must make arrangements with third parties to perform these services, or build our sales, marketing, managerial and other non-technical capabilities. If we are unable to do so, we might not be able to generate product revenue and might not become profitable.

We might obtain future financing through the issuance of debt or equity or other forms of financing, which might have an adverse effect on our shareholders or otherwise adversely affect our business.

If we raise funds through the issuance of debt or equity or other forms of financing, any debt securities or preferred stock issued will have rights, preferences and privileges senior to those of holders of our common stock in the event of liquidation. In such event, there is a possibility that once all senior claims are settled, there might be no assets remaining to pay out to the holders of our common stock. In addition, if we raise funds through the issuance of additional equity, whether through private placements or public offerings, such an issuance would dilute the ownership of our then current shareholders.

The terms of debt securities might also impose restrictions on our operations, which might include limiting our ability to incur additional indebtedness, to pay dividends on or repurchase our capital stock, or to make certain acquisitions or investments. In addition, we might be subject to covenants requiring us to satisfy certain financial tests and ratios, and our ability to satisfy such covenants may be affected by events outside of our control.

Our operating expenses and results and any revenue likely will fluctuate in future periods.

Our revenues and expenses are unpredictable and likely will fluctuate from quarter to quarter due to, among other things, the timing and the unpredictable nature of clinical trials and related expenses, including payments owed by us and to us under collaborative agreements for reimbursement of expenses, future milestone revenues under collaborative agreements, sales of Priligy and Nesina and any future sales of other products. In addition, the recognition of clinical trial and other expenses that we otherwise would recognize over a period of time under applicable accounting principles might be accelerated or expanded in certain circumstances. In such a case, it might cause our expenses during that period to be higher than they otherwise would have been had the circumstances not occurred. For example, if we terminate a clinical trial for which we paid non-refundable upfront fees to a clinical research organization and in which we did not accrue all of the patient costs, the recognition of the expense associated with those fees that we were recognizing as we accrued patient costs would be accelerated and recognized in the period in which the termination occurred.

We are dependent on the performance of service providers.

We rely on service providers, such as contract manufacturers, clinical research organizations, medical institutions and clinical investigators, including physician sponsors, to conduct nearly all of our clinical trials, including recruiting and enrolling patients in the trials. In connection with the spin-off, we entered into a Master Development Services Agreement with PPD pursuant to which PPD provides us clinical development services at discounted rates on a preferred provider basis. If PPD or any of these other parties do not successfully carry out their contractual duties or meet expected deadlines, we might be delayed or may not obtain regulatory approval for or be able to commercialize our product candidates. If any of the third parties upon whom we rely to conduct our clinical trials do not comply with applicable laws, successfully carry out their obligations or meet expected deadlines, our clinical trials might be extended, delayed or terminated.

If the quality or accuracy of the clinical data obtained by third party contractors is compromised due to their failure to adhere to applicable laws or our clinical protocols, or for other reasons, we might not obtain regulatory approval for or successfully commercialize any of our product candidates. If our relationship with any of these organizations or individuals terminates, replacing any of these third parties could delay our clinical trials and could jeopardize our ability to obtain regulatory approvals and commercialize our product candidates on a timely basis, if at all.

Risks Relating to Our Operations**We might not successfully operate the compound partnering business as an independent entity.**

It takes many years for a drug development business like ours to generate revenue and income. Although we have experience operating our compound partnering business within PPD's discovery sciences segment since 1998, we might not be successful in operating this business as a stand-alone company. Generating revenue and income, consistently or at all, from our drug development business and compound partnering activities depends on our ability to:

- develop products internally or obtain rights to them from others on favorable terms;
- successfully complete non-clinical and clinical studies;
- obtain clinical trial materials of sufficient quality or quantity;
- obtain and maintain intellectual property rights to these products;
- obtain and maintain regulatory approvals;
- enter into agreements with third parties to continue the development and commercialization of drug candidates; and
- enter into arrangements with third parties to manufacture products on our behalf and to provide sales and marketing functions.

We must attract and retain key employees in order to succeed.

To be successful, our unique business model requires that our personnel have extensive experience in designing and implementing drug development programs that will run faster than typical studies in the industry. We also require qualified personnel, experienced at building and maintaining relationships with our collaborators. We rely on the services of our senior management, particularly our President and Chief Medical Officer, June Almenoff, our Senior Vice President—Research, Gail McIntyre, and our Senior Vice President—Clinical Operations, Paul Covington, as well as our Chief Financial Officer, Marshall Woodworth, our Vice President—Legal Affairs, Nadine Chien, and our Vice President—Strategic Development, Sailash Patel, the loss of any of whom could adversely impact our operations. We do not carry key man insurance on any of these individuals or any of our other officers or employees. Any inability to hire additional qualified personnel might also require an increase in the workload for both existing and new personnel. We might not be successful in attracting new scientists or management, or in retaining or motivating our existing personnel. The shortage of experienced scientists and managers capable of working within our unique business model might lead to increased recruiting, relocation and compensation costs for these professionals, which might exceed our forecasts. If we are unable to attract and retain any of these personnel, our ability to execute our business plan will be adversely affected.

If our product identification efforts are not successful, we might not be able to effectively develop new products.

Our product candidates are in various stages of development. Some or all of our product candidates might never be developed for any number of reasons, including failure to meet clinical trial tests and failure to receive regulatory approval. For example, we suspended our PPD-10558 program due to unfavorable efficacy data from the Phase II clinical trial. To maintain our business, we need to have a sufficient pipeline of product candidates. Our success in identifying new product candidates depends upon our ability to identify and validate new targets through in-licensing or collaborative arrangements. In order to increase the possibilities of identifying compounds with a reasonable chance for success in clinical studies, part of our business strategy is to identify a higher number of potential targets than we expect to be able to progress through clinical development. If we are unsuccessful in our efforts to identify or obtain rights to new product candidates that lead to the required regulatory approvals and the successful commercialization of products, our business could be harmed.

Many of our drug candidates are in development and we or our collaborators might not be able to obtain regulatory approval for our product candidates.

The development and commercialization of pharmaceutical products are subject to extensive governmental regulation in the United States and foreign countries. Government approvals are required to develop, market and sell the potential drug candidates we develop alone or with others under our risk-sharing arrangements. Especially for the early-stage compounds we target for in-licensing, obtaining government approval to develop, market and sell drug candidates is time-consuming and expensive. Further, clinical trial results for a particular drug candidate might not satisfy requirements to obtain government approvals. For example, in late 2005, Janssen, our collaborator at the time on dapoxetine, received a “not approvable” letter from the FDA. In addition, governmental approvals might not be received in a timely manner, if at all, and we and our collaborative partners might not be able to meet other regulatory requirements for our products. For example, in late 2008, the FDA notified Takeda that it would not be able to complete its review of the alogliptin NDA before the Prescription Drug Use Fee Act date due to the lack of internal resources. In addition, requirements for government approval to market and sell drug candidates are subject to change. For example, the Division of Endocrinologic and Metabolic Drug Products in the Center for Drug Evaluation and Research decided that concerns about cardiovascular risk should be more thoroughly addressed during drug development programs, and, in December 2008, issued final guidance on the topic titled “Guidance for Industry—Diabetes Mellitus—Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes”. As a result, in June 2009 and September 2009, the FDA issued complete responses to Takeda on its NDAs for the alogliptin monotherapy and

the fixed-dose combination of alogliptin and Actos requesting an additional cardiovascular safety trial on alogliptin prior to further regulatory review. Finally, even if we are successful in obtaining all required approvals to market and sell a drug candidate, post-approval requirements and the failure to comply with other regulations could result in suspension or limitation of government approvals.

In connection with drug development activities outside the United States, we and our collaborators will be subject to foreign regulatory requirements governing the testing, approval, manufacture, labeling, marketing and sale of pharmaceutical products. These requirements vary from country to country. Even if approval has been obtained for a product in the United States, approvals in foreign countries must be obtained prior to marketing the product in those countries. The approval process in foreign countries may be more or less rigorous and the time required for approval may be longer or shorter than that required in the United States. Clinical studies conducted outside of any particular country may not be accepted by that country, and the approval of a pharmaceutical product in one country does not assure that the product will be approved in another country.

The failure to gain market acceptance of our product candidates among the medical community would adversely affect our revenue.

Even if approved, our product candidates might not gain market acceptance among physicians, patients, third-party payors and the medical community. We might not achieve market acceptance even if clinical trials demonstrate safety and efficacy and we obtain the necessary regulatory and reimbursement approvals. The degree of market acceptance of any product candidates that we develop will depend on a number of factors, including:

- establishment and demonstration of clinical efficacy and safety;
- cost-effectiveness of our product candidates versus competing products;
- their potential advantage over alternative treatment methods;
- pricing requirements in various markets;
- reimbursement policies of government and third-party payors; and
- marketing and distribution support for our product candidates, including the efforts of our collaborators where they have marketing and distribution responsibilities.

Physicians will not recommend our products until clinical data or other factors demonstrate the safety and efficacy of our product as compared to conventional drug and other treatments. Even if we establish the clinical safety and efficacy of our product candidates, physicians might elect not to use our product for any number of other reasons, including whether the mode of administration of our products is effective for certain indications. The failure of our product candidates to achieve significant market acceptance would materially harm our business, financial condition and results of operations.

We face significant competition.

We face significant competition, including from entities that have substantially greater resources and more experience in the commercialization and marketing of pharmaceuticals than we have. Potential competitors in the United States and other countries include major pharmaceutical and biotechnology companies and specialized pharmaceutical companies. These entities have developed and are developing compounds that might compete with our products in development. These competitors might succeed in more rapidly developing and marketing technologies and products that are more effective than our product candidates or technologies or that would render any future commercialized products or technology obsolete or noncompetitive. Our product candidates and any future commercialized products might also face significant competition from both brand-name and generic manufacturers that could adversely affect any future sales of our products.

Any product that we or our collaborators succeed in developing and for which regulatory approval is obtained must then compete for market acceptance and market share. The relative speed with which we and our collaborators can develop products, complete the clinical testing and approval processes, and supply commercial quantities of the products to the market compared to competitive companies will affect market success. In addition, the amount of marketing and sales resources and the effectiveness of the marketing used with respect to a product will affect its marketing success. Other factors affecting the ability of our products to compete include their efficacy and safety, the manner and frequency of their administration, and the extent of any reimbursement coverage.

In addition, some CRO services providers and private equity funds are developing risk sharing models to finance the pharmaceutical industry's pipeline. As these types of business models evolve, there will be increasing competition for compounds and funds to develop those compounds.

We must protect our patent and other intellectual property rights to succeed.

Our success is dependent in significant part on our ability to develop and protect patent and other intellectual property rights and operate without infringing the intellectual property rights of others.

Our pending patent applications might not result in the issuance of valid patents or the claim scope of our issued patents may not provide competitive advantages. Also, our patent protection might not prevent others from developing competitive products using related or other technology that does not infringe our patent rights. In addition, our patent for Priligy is for method of use and not composition of matter. Further, patent applications are confidential for a period of time after filing. We therefore might not know that a competitor has filed a patent application covering subject matter similar to subject matter in one of our patent applications or that we were the first to invent the innovation we seek to patent. This might lead to disputes including interference proceeding or litigation to determine rights to patentable subject matter. These disputes are often expensive and might result in our being unable to patent an innovation.

The scope, enforceability and effective term of patents can be highly uncertain and often involve complex legal and factual questions and proceedings. No consistent policy has emerged regarding the breadth of claims in pharmaceutical or biotechnology patents, so that even issued patents might later be modified or revoked by the relevant patent authorities or courts. These proceedings could be expensive, last several years and either prevent issuance of additional patents to us or result in a significant reduction in the scope or invalidation of our patents. Any limitation in claim scope could reduce our ability to negotiate future collaborative research and development agreements based on these patents. Moreover, the issuance of a patent in one country does not assure the issuance of a patent with similar claim scope in another country, and claim interpretation and infringement laws vary among countries, so we are unable to predict the extent of patent protection in any country.

In certain cases, we are reliant on our collaborator to file, negotiate and maintain patents covering a licensed product. Our collaborators may fail to adequately obtain and maintain such patents.

In addition to seeking the protection of patents and licenses, we also rely upon trade secrets, know-how and continuing technological innovation that we seek to protect, in part, by confidentiality agreements with employees, consultants, suppliers and licensees. If these agreements are not honored, we might not have adequate remedies for any breach. Additionally, our trade secrets might otherwise become known or patented by our competitors.

We might need to obtain patent licenses from others in order to manufacture or sell our potential products and we might not be able to obtain these licenses on terms acceptable to us or at all.

Other companies, universities and research institutions might obtain patents that could limit our ability to use, import, manufacture, market or sell our products or impair our competitive position. As a result, we might

need to obtain licenses from others before we could continue using, importing, manufacturing, marketing, or selling our products. We might not be able to obtain required licenses on terms acceptable to us, if at all. If we do not obtain required licenses, we might encounter significant delays in product development while we redesign potentially infringing products or methods or we might not be able to market our products at all.

We or our collaborators might not be able to attract a sufficient number of sites or enroll a sufficient number of patients in a timely manner in order to complete our clinical trials.

The rate of completion of clinical trials is significantly dependent upon the rate of patient enrollment. Patient enrollment is a function of many factors, including:

- changing regulatory requirements;
- the size of the patient population;
- perceived risks and benefits of the drug under study;
- availability of competing therapies, including those in clinical development;
- availability of clinical drug supply;
- participation of qualified clinical trial sites;
- availability and willingness of potential participants to enroll in clinical trials;
- design of the protocol;
- proximity of and access by patients to clinical sites;
- patient referral practices of physicians;
- eligibility criteria for the study in question; and
- efforts of the sponsor of and clinical sites involved in the trial to facilitate timely enrollment.

For example, patient enrollment for our Phase II proof-of-concept trial of JNJ-Q2 in hospitalized pneumonia patients was slower than expected. We might have difficulties obtaining sufficient patient enrollment or clinician support to conduct our other clinical trials as planned, and we might need to expend additional funds to obtain access to resources or delay or modify our plans significantly. These considerations might result in our being unable to successfully achieve our projected development timelines, or potentially even lead us to consider the termination of ongoing clinical trials or development of a product for a particular indication.

Changes in the U.S. and international healthcare industry, including reimbursement rates, could adversely affect the commercial value of our development product candidates.

The U.S. and international healthcare industry is subject to changing political, economic and regulatory influences that may significantly affect the purchasing practices and pricing of pharmaceuticals. The laws and regulations governing and issued by applicable regulatory agencies may change and additional government regulations might be enacted, which could prevent or delay regulatory approval of our product candidates. The U.S. Congress adopted healthcare reform and might adopt other legislation that could have the effect of putting downward pressure on the prices that pharmaceutical and biotechnology companies can charge for prescription drugs. Cost-containment measures, whether instituted by healthcare providers or imposed by government health administration regulators or new regulations, could result in greater selectivity in the purchase of drugs. As a result, third-party payors might challenge the price and cost effectiveness of our products. In addition, in many major markets outside the United States, pricing approval is required before sales may commence. As a result, significant uncertainty exists as to the reimbursement status of approved healthcare products.

We might not be able to obtain or maintain our desired price for the products we develop. Any product we introduce might not be considered cost-effective relative to alternative therapies. As a result, adequate third-party reimbursement might not be available to enable us to obtain or maintain prices sufficient to realize an appropriate return on our investment in product development. Also, the trend towards managed healthcare in the United States and the concurrent growth of organizations such as health maintenance organizations, as well as legislative proposals to reform healthcare or reduce government insurance programs, might all result in lower prices, reduced reimbursement levels and diminished markets for our products. These factors will also affect the products that are marketed by our collaborators and licensees. We cannot predict the likelihood, nature or extent of adverse government regulation that might arise from legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we might not be permitted to market our future products and our business could suffer.

Manufacturing changes might result in delays in obtaining regulatory approval or marketing for our products.

If we make changes in the manufacturing process for any of our products, we might be required to demonstrate to the applicable regulatory agencies that the changes have not caused the resulting drug material to differ significantly from the drug material previously produced. Further, any significant manufacturing changes for the production of our product candidates could result in delays in development or regulatory approval or in the reduction or interruption of commercial sales of our product candidates. Our contract manufacturers' inability to maintain manufacturing operations in compliance with applicable regulations within our planned time and cost parameters could materially harm our business, financial condition and results of operations.

We have made manufacturing changes and could make additional manufacturing changes for the production of our products currently in clinical development. These manufacturing changes or an inability to immediately show comparability between the older material and the newer material after making manufacturing changes could result in delays in development or regulatory approvals or in reduction or interruption of commercial sales and could impair our competitive position.

Our business might be harmed if we cannot obtain sufficient quantities of raw materials.

We depend on outside vendors for the supply of raw materials used to produce our product candidates for use in clinical trials. Once a supplier's materials have been selected for use in the manufacturing process, the supplier in effect becomes a sole or limited source of that raw material due to regulatory compliance procedures. If the third-party suppliers were to cease production or otherwise fail to supply us with quality raw materials and we were unable to contract on acceptable terms for these services with alternative suppliers, our ability to produce our products and to conduct preclinical testing and clinical trials of product candidates would be adversely affected. This could impair our competitive position. If the third-party suppliers were to cease production or otherwise fail to supply us with quality raw materials and we were unable to contract on acceptable terms for these services with alternative suppliers, our ability to produce our products and to conduct preclinical testing and clinical trials of product candidates would be adversely affected. This could impair our competitive position.

We must comply with extensive government regulations and laws.

We and our collaboration partners are subject to extensive regulation by federal government, state governments, and the foreign countries in which we conduct our business.

In particular, we are subject to extensive and rigorous government regulation as a developer of drug candidates. For example, the FDA regulates, among other things, the development, testing, research, manufacture, record-keeping, labeling, storage, approval, quality control, adverse event reporting, advertising, promotion, sale and distribution of pharmaceutical products. Our product candidates are subject to extensive regulation by foreign governments. The regulatory review and approval process, which includes preclinical studies and clinical trials of each product candidate, is lengthy, expensive and uncertain.

We must rely on our contract manufacturers and third-party suppliers for regulatory compliance and adhering to the FDA's current Good Manufacturing Practices, or cGMP, requirements. If these manufacturers or suppliers fail to comply with applicable regulations, including FDA pre-or post-approval inspections and cGMP requirements, then the FDA could sanction us. These sanctions could include fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delay, suspension or withdrawal of approvals, license revocation, product seizures or recalls, operational restrictions or criminal prosecutions, any of which could significantly and adversely affect our operating results.

If our operations are found to violate any applicable law or other governmental regulations, we might be subject to civil and criminal penalties, damages and fines. Similarly, if the hospitals, physicians or other providers or entities with which we do business are found non-compliant with applicable laws, they might be subject to sanctions, which could also have a negative impact on us. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations, and additional legal or regulatory change. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation.

We expend a significant amount of resources on compliance efforts and such expenses are unpredictable and might adversely affect our operating results. Changing laws, regulations and standards might also create uncertainty and increase insurance costs. We are committed to compliance and maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment might result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

We might incur significant costs in order to comply with environmental regulations or to defend claims arising from accidents involving the use of hazardous materials.

We are subject to federal, state and local laws and regulations governing the use, discharge, handling and disposal of materials and wastes used in our operations. As a result, we might be required to incur significant costs to comply with these laws and regulations. We cannot eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for any resulting damages and incur liabilities, which exceed our resources. In addition, we cannot predict the extent of the adverse effect on our business or the financial and other costs that might result from any new government requirements arising out of future legislative, administrative or judicial actions.

We might be subject to product liability claims, and our insurance coverage and indemnification rights might not be adequate to cover these claims.

We face an inherent business risk of exposure to product liability and other types of claims in the event that the use of products during research and development efforts or after commercialization results in death, personal injury or other adverse effects.

Pre-clinical and clinical trials are conducted during the development of our drug candidates to determine the safety and efficacy of potential products for use by humans following approval by regulatory authorities. Despite our efforts to determine the safety of our drug candidates in pre-clinical studies and use of clinical study protocols approved by regulators, unanticipated negative side effects might become evident only when the drug candidates have been delivered to humans during clinical trials or used by patients in the marketplace.

This risk exists even with respect to any products that receive regulatory approval for commercial sale. While we will procure and maintain liability insurance with coverage up to \$10.0 million per occurrence and in

the aggregate and generally have indemnification rights under our collaboration agreements, our insurance might not be sufficient to satisfy any or all liabilities that may arise and our indemnification rights might not apply or be sufficient to cover such claims. Also, adequate insurance coverage might not be available in the future at acceptable cost, if at all.

Our operations might be affected by the occurrence of a natural disaster or other catastrophic event.

We depend on our collaboration partners, service providers and other facilities for the continued operation of our business. Natural disasters or other catastrophic events, including terrorist attacks, pandemic flu, hurricanes and ice storms, could disrupt our operations or those of our collaboration partners, which could also affect us. Even though we carry business interruption insurance policies and typically have provisions in our contracts that protect us in certain events, we might suffer losses as a result of business interruptions that exceed the coverage available under our insurance policies or for which we do not have coverage. Any natural disaster or catastrophic event affecting us or our collaboration partners could have a significant negative impact on our operations and financial performance.

We must protect electronic information and assets to succeed.

We rely on critical and sensitive data, such as personally identifiable patient information, trade secrets, intellectual property and corporate strategic plans. Security of this type of data is exposed to increasing external threats. We are also subject to various standards for the protection of personally identifiable information. Failure to implement appropriate safeguards to adequately protect against any unauthorized or unintentional access, acquisition, use, modification, loss or disclosure of this critical or sensitive data may adversely affect our operations.

Risks Resulting from Our Spin-Off From PPD

Our historical financial information is not necessarily indicative of our future financial position, future results of operations or future cash flows and does not reflect what our financial position, results of operations or cash flows would have been as a stand-alone company during the periods presented.

Our historical financial information included in this Form 10-K does not necessarily reflect what our financial position, results of operations or cash flows would have been as a stand-alone publicly traded company during the periods presented prior to June 2010. In addition, it is not necessarily indicative of our future financial position, future results of operations or future cash flows. This is primarily a result of the following factors:

- Prior to our separation, our business was operated by PPD as part of its broader corporate organization and we did not operate as a stand-alone company;
- Most general administrative functions were performed by PPD for the combined entity, so although our historical combined financial statements reflect allocations of costs for services shared with PPD, these allocations may differ from the costs we will incur for these services as an independent company;
- After the completion of our separation, the cost of capital for our business might be higher than PPD's cost of capital prior to our separation; and
- Prior to the separation, our financial statements include revenues and expenses of services that we did not continue subsequent to the separation.

We have a limited history operating as an independent company upon which you can evaluate us.

We have a limited operating history as a stand-alone entity. While our compound partnering business has constituted a part of the historic operations of PPD since 1998, we have only operated as a stand-alone company without the CRO Business since June 2010. Following the spin-off, as an independent company, our ability to

satisfy our obligations and achieve profitability will be solely dependent upon the future performance of our compound partnering business, and we will not be able to rely upon the capital resources and cash flows of the CRO Business remaining with PPD.

We might have received better terms from unaffiliated third parties than the terms we receive in our agreements with PPD.

The agreements we entered into with PPD in connection with the spin-off, including the Master Development Services Agreement, the sublease, the Employee Matters Agreement and the Transition Services Agreement, were negotiated while we were still part of PPD. The terms of these agreements relate to, among other things, drug development services to be provided to us by PPD, the subleasing of our offices, employee benefit matters and the provision of transition services to us by PPD. The Master Development Services Agreement requires us to use PPD for specified drug development services for three years contingent on PPD's expertise and capabilities to provide the needed services. While we believe the terms and conditions of these agreements with PPD are reasonable and acceptable to us, they might not reflect the same terms and conditions that we could have obtained had we sought competitive bids from and negotiated with unaffiliated parties.

Risks Relating to Our Common Stock

Various factors could negatively affect the market price or market of our common stock, which has traded publicly since June 2010.

Our stock has a limited trading history because we only became a separate public company in June 2010, which could make investing in our stock riskier than more established companies. In addition, market prices for securities of pharmaceutical companies have been highly volatile, and we expect such volatility to continue for the foreseeable future, so that investment in our securities involves substantial risk. Additionally, the stock market from time to time has experienced significant price and volume fluctuations unrelated to the operating performance of particular companies. The following are some of the factors that might have a significant effect on the market price of our common stock:

- developments or disputes as to patent or other proprietary rights;
- approval or introduction of competing products and technologies;
- results of clinical trials;
- failures or unexpected delays in timelines for our potential products in development, including the obtaining of regulatory approvals;
- delays in manufacturing or clinical trial plans;
- fluctuations in our operating results;
- market reaction to announcements by other biotechnology or pharmaceutical companies;
- initiation, termination or modification of agreements with our collaborators or disputes or disagreements with collaborators;
- loss of key personnel;
- litigation or the threat of litigation;
- public concern as to the safety of drugs developed by us;
- sales of our common stock held by our directors and executive officers; and
- comments and expectations of results made by securities analysts or investors.

If any of these factors causes us to fail to meet the expectations of securities analysts or investors, or if adverse conditions prevail or are perceived to prevail with respect to our business, the price of our common stock would likely drop significantly. A significant drop in the price of a company's common stock often leads to the filing of securities class action litigation against such a company. This type of litigation against us could result in substantial costs and a diversion of management's attention and resources.

Your percentage ownership in Furiex might be diluted in the future.

Your percentage ownership in Furiex might be diluted in the future because of equity awards that we expect will be granted to our directors, officers and employees, as well as any future equity financing.

Provisions in our amended and restated certificate of incorporation and bylaws and of Delaware law might prevent or delay an acquisition of our company, which could decrease the trading price of our common stock.

Our amended and restated certificate of incorporation, bylaws and Delaware law contain provisions that are intended to deter coercive takeover practices and inadequate takeover bids by making such practices or bids unacceptably expensive to the raider and to encourage prospective acquirors to negotiate with our Board rather than to attempt a hostile takeover. These provisions include, among others:

- no right of our shareholders to act by written consent;
- procedures requiring advance notice of shareholder proposals or nominations for directors for election at shareholder meetings;
- the right of our Board to issue preferred stock without shareholder approval; and
- no shareholder rights to call a special shareholders meeting.

Delaware law also imposes some restrictions on mergers and other business combinations between us and any holder of 15% or more of our outstanding common stock.

We believe these provisions protect our shareholders from coercive or otherwise unfair takeover tactics by requiring potential acquirors to negotiate with our Board and by providing our Board with more time to assess any acquisition proposal. These provisions are not intended to make our company immune from takeovers. However, these provisions apply even if the offer might be considered beneficial by some shareholders and could delay or prevent an acquisition that our Board determines is not in the best interests of our company and our shareholders.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our headquarters is located in Morrisville, North Carolina, where we occupy approximately 4,650 square feet of office space under a lease expiring in 2012. We have the option to extend the term of our lease from PPD for up to one year. We own substantially all of the equipment used in our facilities.

Item 3. Legal Proceedings

In the normal course of business, we might be a party to various claims and legal proceedings. As of this time, there are no outstanding claims that management believes will have a material effect upon our financial condition, results of operations or cash flows.

Item 4. Mine Safety Disclosures

Not applicable.

Executive Officers of the Registrant

The following table sets forth information regarding individuals who serve as our executive officers, including their positions.

Name	Age	Position
June S. Almenoff	55	President and Chief Medical Officer
Gail F. McIntyre	49	Senior Vice President-Research
Paul S. Covington	56	Senior Vice President-Clinical Development and Operations
Marshall H. Woodworth	54	Chief Financial Officer, Treasurer and Assistant Secretary

June S. Almenoff has served as our President and Chief Medical Officer since March 2010. Dr. Almenoff led our spin-off from PPD and has overseen the successful delivery of our pipeline assets through Proof-of-Concept development. Prior to joining Furiex, Dr. Almenoff had over 12 years of pharmaceutical industry experience at GlaxoSmithKline, or GSK, from 1997 to 2010. Most recently, she was Vice President in the Clinical Safety organization at GSK, where she served on the company's senior governing medical boards and managed a diverse therapeutic portfolio supporting numerous regulatory approvals. Dr. Almenoff led the GSK teams that developed three pioneering systems for minimizing risk in early- and late-stage drug development, which have been widely implemented by pharmaceutical companies and regulatory agencies, and their impact on the industry has been recognized by the Wall Street Journal Technology Innovation Award and several other prestigious awards. She also led the scientific diligence effort for GSK's acquisition of Stiefel Laboratories and established a licensing program for a drug development unit. During her tenure at GSK, also Dr. Almenoff chaired a Pharma-FDA working group. Prior to joining GSK, Dr. Almenoff was on the faculty of Duke University Medical Center. Dr. Almenoff received her B.A. *cum laude* from Smith College. She graduated from the M.D.-Ph.D. program at the Mt. Sinai School of Medicine and completed a residency in Internal Medicine and a Fellowship in Infectious Diseases at Stanford University Medical Center. Dr. Almenoff is a board-certified Fellow of the American College of Physicians with 10 years of clinical practice experience; she has authored over 45 publications.

Gail F. McIntyre has served as our Senior Vice President—Research since April 2010. Prior to joining us, Dr. McIntyre was with PPD for 12 years and served as head of the company's compound partnering business from October 2003 until joining Furiex in 2010. Dr. McIntyre has more than 19 years of experience in the drug discovery and development industry. Her experience covers multiple therapeutic areas including oncology, infectious diseases, central nervous system and metabolic/endocrine as well as various therapies including small drugs, treatment vaccines, immunomodulators, antibodies, immunoconjugates and peptide mimetics. Dr. McIntyre has prepared more than 30 regulatory submissions and ushered compounds through the lead optimization phase to early drug development and from early drug development through the IND and NDA phases. Dr. McIntyre earned a bachelor's degree in biology from Merrimack College. Both her master's degree and doctorate are in biochemistry and biophysics from the University of North Carolina at Chapel Hill. Dr. McIntyre is board certified in clinical pathology (hematology and clinical chemistry) and toxicology. She is a member of the American College of Toxicology, the American Society of Clinical Pathologists, the Drug Information Association and the American Association for the Advancement of Science.

Paul S. Covington became our Senior Vice President-Clinical Development and Operations in January 2010. Dr. Covington has more than 17 years of drug development experience. As PPD's Executive Vice President and Chief Medical Officer from 2002 to 2008, he designed and implemented the development programs for all PPD's compound partnering alliances. Dr. Covington was responsible for the successful Phase I and Phase II development of Priligy and Alogliptin, both of which were partnered to large pharmaceutical companies following completion of the proof-of-concept studies. As part of his contribution to PPD's compound

partnering programs, Dr. Covington also participated in joint development committees with each alliance partner. At PPD, Dr. Covington also oversaw all aspects of medical and regulatory affairs services for quality drug development including pharmacovigilance, medical writing and program management. He was at the forefront of establishing monitoring processes for patient safety and data integrity for complex studies involving extremely ill patients. Dr. Covington joined PPD in 1991 as a Medical Director. From 2008 to 2010, Dr. Covington was an independent consultant. Prior to joining PPD, Dr. Covington served in various medical roles in both hospital and private practice settings, where he was lead investigator in multiple protocols. He was medical director at Future HealthCare Research Centers in Birmingham, Alabama from 1991 to 1992, and chief of staff, director of cardio respiratory and director of critical care at Central Alabama Community Hospital from 1985 to 1990. He completed his residency at Carraway Methodist Medical Center in Birmingham. Dr. Covington received his bachelor's and medical degrees from the University of Alabama in Birmingham.

Marshall H. Woodworth has served as our Chief Financial Officer, Treasurer and Assistant Secretary since February 2011. He joined us in January 2010 as our Vice President—Finance and Treasurer. Mr. Woodworth has more than 24 years of financial experience of which more than 14 years were in pharmaceutical and life science-related companies. Mr. Woodworth served as Vice President of Finance with Xerium Technologies, Inc. from 2006 to 2009. He served in various financial management roles with Milliken & Company including Division Finance Leader and European Financial Leader from 2000 to 2006. Prior to Milliken & Company, Mr. Woodworth held various financial management positions with Monsanto, Dow Chemical, and Eli Lilly. Mr. Woodworth received his bachelor's degree in science from the University of Maryland and an M.B.A. from the Indiana University at Bloomington. He is a Certified Management Accountant and Certified Financial Manager.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is traded under the symbol "FURX" and is quoted on the Nasdaq Global Market. The following table sets forth the high and low sales prices for shares of our common stock, as reported by Nasdaq for the periods indicated.

		<i>2011</i>	
		<i>High</i>	<i>Low</i>
<i>First Quarter</i>	<i>\$17.41</i>	<i>\$14.00</i>
<i>Second Quarter</i>	<i>\$19.55</i>	<i>\$13.76</i>
<i>Third Quarter</i>	<i>\$19.26</i>	<i>\$13.58</i>
<i>Fourth Quarter</i>	<i>\$18.87</i>	<i>\$12.25</i>

		<i>2010</i>	
		<i>High</i>	<i>Low</i>
<i>First Quarter*</i>	<i>\$ —</i>	<i>\$ —</i>
<i>Second Quarter*</i>	<i>\$20.00</i>	<i>\$ 8.69</i>
<i>Third Quarter</i>	<i>\$11.95</i>	<i>\$ 9.29</i>
<i>Fourth Quarter</i>	<i>\$15.61</i>	<i>\$10.94</i>

* Our common stock began trading on the Nasdaq Global Market on May 28, 2010, on a "when-issued" basis. On June 15, 2010, the first trading day after the distribution, "when-issued" trading with respect to our common stock ended and "regular way" trading began. As a result, our stock was not listed in the first quarter of 2010 and only listed for twenty-three trading days in the second quarter of 2010.

The information required by Item 5 of Form 10-K regarding shares subject to outstanding options or warrants to purchase common stock is incorporated herein by reference to "Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters."

Holder

As of February 29, 2012 there were 169 stockholders of record, which excludes stockholders whose shares were held in nominee or street name by brokers.

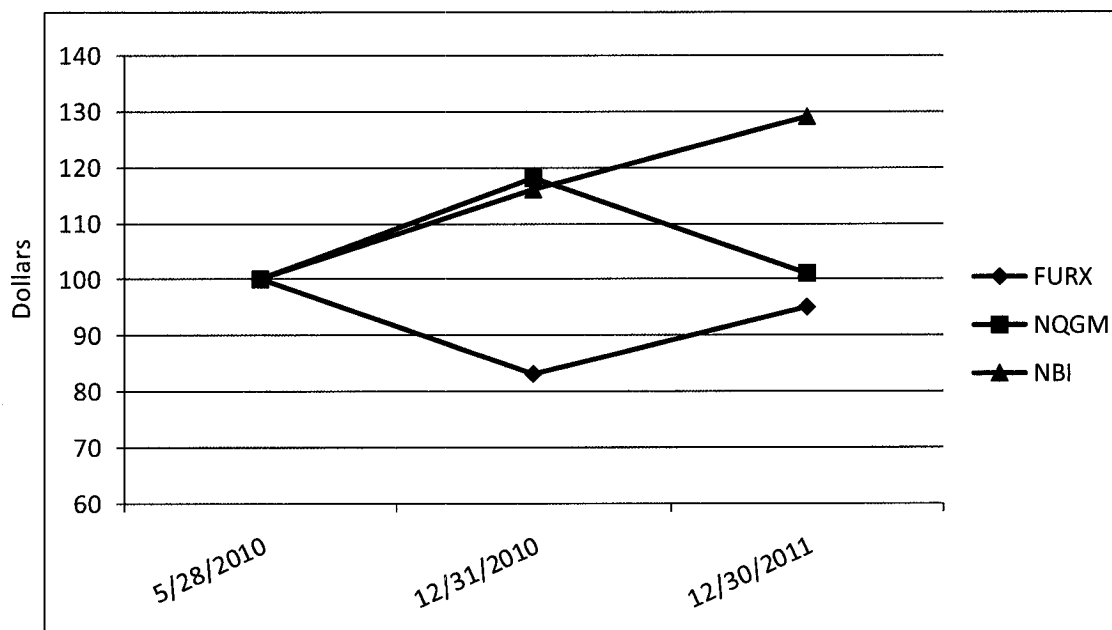
On February 29, 2012 the closing price for the common stock as reported on the Nasdaq Global Market was \$18.04.

Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to "Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters."

Performance Graph

The following graph compares our cumulative total stockholder return from May 28, 2010, when our common stock began trading on a “when issued” basis, with those of the Nasdaq Global Market Composite Index (NQGM) and the Nasdaq Biotechnology Index (NBI). The graph assumes that U.S. \$100 was invested on May 28, 2010 in (1) our common stock, (2) the Nasdaq Global Market Composite Index and (3) the Nasdaq Biotechnology Index. The measurement points utilized in the graph consist of the last trading day in each calendar year, which closely approximates the last day of the respective fiscal year of the Company. The historical stock performance presented below is not intended to and may not be indicative of future stock performance.



	<u>5/28/10</u>	<u>12/31/10</u>	<u>12/31/11</u>
FURX	\$100	\$ 83	\$ 95
Nasdaq Global Market Composite Index	\$100	\$118	\$101
Nasdaq Biotech Index	\$100	\$116	\$129

Dividends

We have never declared or paid cash dividends on our common stock. We currently expect to retain future earnings, if any, for use in the operation and expansion of the business and do not anticipate paying any cash dividends in the foreseeable future.

Item 6. Selected Financial Data

The tables below set forth selected historical financial information of the Company that has been derived from the audited financial statements as of December 31, 2008, 2009, 2010 and 2011, and for the five years in the period ended December 31, 2011, as well as from the Company's unaudited financial statements as of December 31, 2007. For all periods presented prior to December 31, 2010, the weighted-average shares outstanding are calculated based on the 9,881,340 shares issued in connection with the spin-off on June 14, 2010.

The selected historical financial data should be read in conjunction with the combined and consolidated financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations", included elsewhere in this Form 10-K.

Combined and Consolidated Statements of Operations Data:

(in thousands, except per share data)	Year Ended December 31,				
	2007	2008	2009	2010	2011
Total revenue	\$ 560	\$18,419	\$ 6,312	\$ 8,983	\$ 4,490
Operating expenses	23,316	11,645	14,621	58,504	53,046
Income (loss) from operations ⁽¹⁾	(22,756)	6,774	(8,309)	(49,521)	(48,556)
Interest expense	—	—	—	—	413
Other income, net	19	14	10	9	2
Provision for income taxes	—	—	—	14	14
Income (loss) from continuing operations	(22,737)	6,788	(8,299)	(49,526)	(48,981)
Discontinued operations, net ⁽²⁾	(185)	(976)	(632)	(5,133)	—
Net income (loss)	<u>\$(22,922)</u>	<u>\$ 5,812</u>	<u>\$(8,931)</u>	<u>\$(54,659)</u>	<u>\$(48,981)</u>
Income (loss) from continuing operations per basic and diluted share	\$ (2.30)	\$ 0.69	\$ (0.84)	\$ (5.01)	\$ (4.96)
Loss from discontinued operations, net of income taxes per basic and diluted share	\$ (0.02)	\$ (0.10)	\$ (0.06)	\$ (0.52)	\$ —
Net income (loss) per basic and diluted share	\$ (2.32)	\$ 0.59	\$ (0.90)	\$ (5.53)	\$ (4.96)
Weighted-average shares used to compute net income (loss) per basic and diluted share:	9,881	9,881	9,881	9,881	9,884

Combined and Consolidated Balance Sheet Data:

(in thousands)	As of December 31,				
	2007	2008	2009	2010	2011
Total assets	63,265	61,138	55,877	132,559	95,124
Total debt	—	—	—	—	10,000
Total shareholders' equity	—	—	—	118,504	74,323
PPD net investment ⁽³⁾	56,870	55,524	49,270	—	—

- (1) Impairments of intangible assets are included in income (loss) from operations. For 2009, the impairment of intangible asset was related to in-process research and development for the MAG-131 compound obtained through the acquisition of Magen Biosciences, Inc. For 2008, the impairment of intangible asset related to the remaining unamortized value of our royalty interest in SinuNase and other Accentia antifungal products.
- (2) In 2009, PPD completed dispositions of Piedmont Research Center, LLC and PPD Biomarker Discovery Sciences, LLC. Results of operations for these dispositions are included in discontinued operations. In May 2010, PPD closed the dermatology therapeutic discovery unit, PPD Dermatology, Inc., formerly Magen Biosciences, Inc.
- (3) Prior to June 14, 2010, the financial statements of the company represent a combination of various components of PPD comprising the Discovery Sciences segment. Because a direct ownership relationship did not exist among all the components comprising the company prior to the spin-off, PPD's net investment in the company is shown within the statements of shareholders' equity in the combined and consolidated financial statements prior to December 31, 2010. The net investment account represents the cumulative investments in, distributions from and earnings (loss) of the company.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

This Form 10-K includes forward-looking statements. All statements other than statements of historical facts are forward-looking statements, including any projections of milestones, royalties or other financial items, any statements of the plans and objectives of management for future operations, any statements concerning research and development, clinical development timelines, proposed new products or licensing or collaborative arrangements, any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as "believes", "might", "will", "expects", "plans", "anticipates", "estimates", "potential" or "continue", or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained in this Form 10-K are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including the risk factors set forth in Item 1A, and for the reasons described elsewhere in this Form 10-K, any of which could significantly adversely impact our business. All forward-looking statements and reasons why results might differ included in this Form 10-K are made as of the date hereof, and we assume no obligation to update these forward-looking statements or reasons why actual results might differ.

Results of Operations

On June 14, 2010 we became an independent company upon the spin-off by Pharmaceutical Product Development, Inc. As part of and prior to the spin-off, PPD transferred to us \$100.0 million in cash and current accounts receivable and payable associated with the compound partnering business.

Our business consists solely of compound development and partnering activities. Accordingly, we operate in one reportable business segment. Historically, our revenues consisted primarily of milestone and royalty payments from collaborators from out-licensed compounds. For the year ended December 31, 2010, our year-to-date revenue includes \$7.5 million in regulatory approval milestones resulting from regulatory and pricing approval of Nesina in Japan in addition to \$1.3 million in royalty revenue from the sale of Priligy and Nesina by our collaborators, Alza and Takeda. For the year ended December 31, 2011, our year-to-date revenue of \$4.5 million is comprised of royalty revenue from the sale of Priligy and Nesina/Liovel by our collaborators, Alza and Takeda.

We incurred research and development expenses of \$50.1 million and \$44.2 million for the years ended December 31, 2010 and 2011, respectively. Our research and development expenses include costs incurred for our clinical-stage drug candidates, including the statin, PPD-10558, and the two compounds in-licensed from Janssen. We expect our level of research and development expenditures related to Phase II studies to decline significantly over the next quarter as work on our various Phase II studies comes to completion. We currently expect expenses associated with the continued development of MuDelta to be between \$30.0 and \$35.0 million over the next year related to Phase III costs. These expenses include contract research organization services provided by PPD, non-clinical testing and clinical trial material manufacturing provided by third parties, and the direct cost of our personnel managing the programs and payments to third parties. All research and development expenses for our drug candidates and external collaborations are expensed as incurred.

The timing and amount of any future expenses, completion dates and revenues related to our drug candidates are subject to significant uncertainty due to the nature of our development programs. We do not know if we will be successful in developing any of our drug candidates. The timing and amount of our research and development expenses will depend upon the costs associated with the present and potential future clinical trials of our drug candidates, any related expansion of our research and development organization, regulatory requirements, advancement of our pre-clinical programs and manufacturing costs. There are numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of events arising during clinical development. For example, if the FDA or another regulatory

authority were to require us to conduct clinical trials beyond those which we currently anticipate to complete clinical development of a drug candidate, or if we experience significant delays in enrollment in any of our clinical trials, we would be required to expend significant additional financial resources and time on the completion of clinical development. The timing and amount of revenues, if any, are equally dependent upon the success of the clinical trials as well as the commercial success of these products in the marketplace, all of which are subject to a variety of risk factors and uncertainties.

For the year ended December 31, 2011, we reported an operating loss of \$48.6 million and net loss of \$49.0 million. We expect to continue to incur net losses until revenues from all sources reach a level sufficient to support our ongoing operations.

Our business is subject to various risks and uncertainties. See “Risk Factors” described in Part 1 Item A for information on these risks and uncertainties.

Basis of Accounting

The accompanying combined financial statements for periods prior to June 14, 2010, have been derived from the combined financial statements and accounting records of PPD, and from the historical cost basis of the assets and liabilities of the various activities that reflect the combined results of operations, financial condition and cash flows of the discovery sciences segment of PPD. All the business components of the discovery sciences segment have been included in the historical statements because they were managed by common PPD segment management, and because they reflected historical performance of segment management.

In May 2010, PPD discontinued operations of its wholly owned subsidiary PPD Dermatology, Inc., formerly Magen Biosciences, Inc., due to unfavorable efficacy data associated with the MAG-131 program. This business unit is recorded as discontinued operations in the statements of operations. Additionally, the discovery sciences segment included pre-clinical consulting services not offered by us. All rights and obligations related to pre-clinical consulting services and the definitive purchase agreements related to PPD Dermatology, Inc. have been retained by PPD.

For periods prior to the June 14, 2010 spin-off, we were allocated expenses from PPD such as executive oversight, risk management, accounting, tax, legal, investor relations, human resources, information technology, facilities and depreciation, but were not allocated the underlying productive assets, such as information systems equipment, and furniture and facilities that were not assigned to us, but from which we have benefited. Such expenses have been reflected in the combined and consolidated financial statements as expense allocations from PPD. The basis of these allocations included full-time equivalent employees for the respective periods presented and square footage of occupied space. See Note 14 to our combined and consolidated financial statements for further discussion of the allocations.

Management believes that the assumptions and allocations underlying the combined and consolidated financial statements are reasonable. For periods prior to the June 14, 2010 spin-off, the financial information in these combined and consolidated financial statements does not include all expenses that would have been incurred had we been a separate, stand-alone publicly traded entity. For periods prior to the June 14, 2010 spin-off, the combined and consolidated financial statements include assets, liabilities and operations for PPD Dermatology, Inc. and pre-clinical consulting services that are not included in our operations after the spin-off. As a result, the financial information herein does not reflect our financial position, results of operations or cash flows had we been a separate, stand-alone entity during the historical periods presented.

Year Ended December 31, 2010 versus Year Ended December 31, 2011

The following table sets forth amounts from our combined and consolidated financial statements for the year ended December 31, 2010 compared to the year ended December 31, 2011.

(in thousands)	Year Ended December 31,	
	2010	2011
Revenue:		
Milestones	\$ 7,500	\$ —
Royalties	1,330	4,490
Service	75	—
Other	78	—
Total revenue	<u>8,983</u>	<u>4,490</u>
Direct expenses	21	—
Research and development expenses	50,112	44,202
Selling, general and administrative expenses	8,262	8,761
Depreciation and amortization	109	83
Total operating expenses	<u>58,504</u>	<u>53,046</u>
Operating loss	(49,521)	(48,556)
Interest expense	—	413
Other income, net	9	2
Loss from continuing operations before provision for income taxes	(49,512)	(48,967)
Provision for income taxes	14	14
Loss from continuing operations	(49,526)	(48,981)
Loss from discontinued operations, net of income taxes	(5,133)	—
Net loss	<u><u>\$(54,659)</u></u>	<u><u>\$(48,981)</u></u>

Revenue

Total revenue decreased \$4.5 million to \$4.5 million for the year ended December 31, 2011 from 2010. The decrease in total revenue was primarily attributable to a \$7.5 million decrease in milestone revenue we earned in 2010 as a result of regulatory and pricing approvals of Nesina in Japan, partially offset by an increase of \$3.2 million in royalty revenue from 2010 based on the sale of approved products by our collaborators. For the year ended December 31, 2011, we received royalties of \$4.5 million from sales of Priligy in various countries outside the United States, and from the sale of Nesina and Liovel in Japan.

Expenses

Research and development, or R&D, expenses decreased \$5.9 million to \$44.2 million for the year ended December 31, 2011 from 2010. The decrease in R&D expense was due predominantly to reduced development costs for the MuDelta and JNJ-Q2 compounds offset by increased spending related to the PPD-10558 compound.

The following table sets forth amounts from our combined and consolidated statements of operations for R&D expenses along with the dollar amount of the changes for the year ended December 31, 2010 compared to the year ended December 31, 2011.

(in thousands)	Year Ended December 31,		\$ Inc (Dec)
	2010	2011	
R&D expense by project:			
MuDelta	\$24,670	\$15,954	\$(8,716)
JNJ-Q2	22,668	12,787	(9,881)
PPD-10558	1,197	12,873	11,676
Other R&D expense	1,577	2,588	1,011
Total R&D expense	<u>\$50,112</u>	<u>\$44,202</u>	<u>\$(5,910)</u>

As of December 31, 2011, we have substantially completed the Phase II clinical trials for the MuDelta and JNJ-Q2 compounds.

On April 18, 2011, Janssen announced that in connection with a broad strategic review of its portfolio of infectious disease programs, it will be redirecting its research and development efforts toward antivirals and vaccines, and will not be investing in the development of new antibacterial therapies. As a result, Janssen elected not to exercise its option to continue the development of the JNJ-Q2 compound. On April 19, 2011, we announced that we had acquired full exclusive license rights to develop and commercialize the JNJ-Q2 compound under our existing development and license agreement with Janssen. On November 1, 2011, we announced we had acquired full exclusive license rights to develop and commercialize the MuDelta compound under our existing development and license agreement with Janssen. We acquired these rights as a result of Janssen's decision not to exercise its option under the agreement to continue development of MuDelta. We plan to continue evaluating other partnering and funding opportunities for both the JNJ-Q2 and MuDelta compounds.

In December 2011, we announced top-line results from the Phase II trial of PPD-10558. Based on these results, we have discontinued further spending on the PPD-10558 program and plan to terminate the license agreement with Ranbaxy in accordance with the terms of the agreement. We will owe Ranbaxy a \$1.0 million development milestone payment upon completion of the Phase II final study report, which is expected to occur in the second quarter of 2012.

R&D expenses may fluctuate significantly from period to period for a variety of reasons, including the number of compounds under development, the stages of development and changes in development plans. We currently expect expenses associated with the continued development of MuDelta to be between \$30.0 and \$35.0 million over the next year related to Phase III costs.

Selling, general and administrative, or SG&A expenses, increased \$0.5 million to \$8.8 million for the year ended December 31, 2011 from 2010.

Income Taxes

During 2010 and 2011, we did not record a tax benefit related to our operating losses because we have provided full valuation allowances against our assets based on our history of operating losses. Additionally, with the exception of the pre-acquisition federal and state tax filings for Magen BioSciences, Inc. and certain separate state filings, through the June 14, 2010 spin-off, our operations were included in the consolidated federal and combined state tax returns of PPD, and the resulting tax attributes have been fully utilized by PPD and are no longer available to us for future use. Subsequent to June 14, 2010, we have filed federal and state returns separately from PPD and can use our tax attributes accordingly. However, we anticipate that we will require a full valuation allowance against any deferred tax assets until such time as we are able to demonstrate a consistent

pattern of profitability. For the years ended December 31, 2010 and 2011, we recorded an insignificant amount of income tax expense. This amount relates to the adjustment of a deferred tax liability associated with historical goodwill, which is amortized and deductible for tax purposes, but is an indefinite-lived intangible asset for financial reporting purposes.

Results of Operations

Operating loss decreased \$0.9 million from a loss of \$49.5 million in 2010 to a loss of \$48.6 million in 2011. This decrease in loss from operations resulted primarily from the \$5.9 million decrease in R&D expense, offset by the \$4.5 million decrease in revenue, as described above.

Net loss of \$49.0 million in 2011 represents a \$5.7 million decrease from net loss of \$54.7 million in 2010. This decrease in net loss resulted primarily from discontinued operations, in addition to changes in revenue and R&D described above. In May 2010, PPD discontinued operations of its wholly owned subsidiary PPD Dermatology, Inc. due to unfavorable efficacy data associated with the MAG-131 program. As a result, this business unit is shown as discontinued operations for 2010. Loss from discontinued operations was \$5.1 million for the year ended December 31, 2010.

Year Ended December 31, 2009 versus Year Ended December 31, 2010

The following table sets forth amounts from our combined and consolidated financial statements for the year ended December 31, 2009 compared to the year ended December 31, 2010.

(in thousands)	Year Ended December 31,	
	2009	2010
Revenue:		
Milestones	\$ 5,000	\$ 7,500
Royalties	923	1,330
Service	389	75
Other	—	78
Total revenue	<u>6,312</u>	<u>8,983</u>
Direct expenses	265	21
Research and development expenses	11,795	50,112
Selling, general and administrative expenses	2,551	8,262
Depreciation and amortization	10	109
Total operating expenses	<u>14,621</u>	<u>58,504</u>
Operating loss	(8,309)	(49,521)
Other income, net	10	9
Loss from continuing operations before provision for income taxes	(8,299)	(49,512)
Provision for income taxes	—	14
Loss from continuing operations	(8,299)	(49,526)
Loss from discontinued operations, net of income taxes	(632)	(5,133)
Net loss	<u><u>\$ (8,931)</u></u>	<u><u>\$ (54,659)</u></u>

Revenue

Total revenue increased \$2.7 million to \$9.0 million for the year ended December 31, 2010 from 2009. The increase in total revenue was primarily attributable to a \$2.5 million increase in milestone revenue from the \$7.5 million milestone payment we earned as a result of regulatory and pricing approvals of Nesina in Japan,

partially offset by a non-recurring milestone payment in 2009 of \$5.0 million earned as a result of regulatory approvals of Priligy in Finland and Sweden. Royalty revenue is based on the sale of approved products by our collaborators. For the year ended December 31, 2010, we received royalties of \$1.3 million from sales of Priligy in various countries outside the United States, and from the sale of Nesina in Japan. Service revenues were related to consulting services provided to customers of PPD. All service contracts remained with PPD upon the spin-off.

Expenses

R&D expenses increased \$38.3 million to \$50.1 million for the year ended December 31, 2010 from 2009. The increase in R&D expense was primarily due to development costs related to the two therapeutic compounds in-licensed from Janssen in November 2009, partially offset by the \$7.0 million of in-licensing payments related to these compounds paid to Janssen in 2009.

The following table sets forth amounts from our combined and consolidated statements of operations for R&D expenses along with the dollar amount of the changes for the year ended December 31, 2009 compared to the year ended December 31, 2010.

(in thousands)	Year Ended December 31,		\$ Inc (Dec)
	2009	2010	
R&D expense by project:			
MuDelta	\$ 572	\$24,670	\$24,098
JNJ-Q2	1,595	22,668	21,073
PPD-10558	1,288	1,197	(91)
Upfront payments to Janssen	7,000	—	(7,000)
Other R&D expense	1,340	1,577	237
Total R&D expense	<u>\$11,795</u>	<u>\$50,112</u>	<u>\$38,317</u>

SG&A expenses increased \$5.7 million to \$8.3 million for the year ended December 31, 2010 from 2009. The increase in SG&A expenses was the result of \$2.6 million in costs incurred in connection with the spin-off, additional costs associated with being a stand-alone publicly traded company, including increases in professional service fees, and increases in stock compensation expense.

Results of Operations

Operating loss increased \$41.2 million from a loss of \$8.3 million in 2009 to a loss of \$49.5 million in 2010. This increase in loss from operations resulted primarily from the \$38.3 million increase in R&D expense and the \$5.7 million increase in SG&A, as described above, partially offset by an increase of \$2.7 million in revenue.

In May 2009, PPD completed the disposition of substantially all of the assets of Piedmont Research Center, LLC. Piedmont Research Center, LLC provided pre-clinical research services for clients with anti-cancer agents and other therapeutic candidates. In December 2009, PPD completed the disposition of its wholly owned subsidiary, PPD Biomarker Discovery Sciences, LLC. PPD Biomarker Discovery Sciences, LLC provided biomarker discovery services and participant sample analysis. In May 2010, PPD discontinued operations of its wholly owned subsidiary PPD Dermatology, Inc. due to unfavorable efficacy data associated with the MAG-131 program. As a result, these business units are shown as discontinued operations for 2009 and 2010. Loss from discontinued operations was \$0.6 and \$5.1 million for the year ended December 31, 2009 and 2010, respectively.

Net loss of \$54.7 million in 2010 represents a \$45.8 million increase from net loss of \$8.9 million in 2009. This increase in net loss resulted primarily from the \$38.3 million increase in R&D expense, the \$5.7 million increase in SG&A expense, and the \$4.5 million increase in loss from discontinued operations, partially offset by an increase of \$2.7 million in revenue.

Liquidity and Capital Resources

As of December 31, 2011, we had \$43.6 million of cash, cash equivalents and short-term investments. The primary source of our cash is the \$100.0 million PPD provided us upon the spin-off on June 14, 2010, \$11.1 million of cash received related to milestone and royalty revenues since the spin-off and cash from the issuance of debt. On August 18, 2011, we entered into a Loan and Security Agreement with MidCap Funding III, LLC and Silicon Valley Bank. The loan agreement is structured in two tranches. The first tranche in the amount of \$10.0 million was drawn upon closing of the transaction. The second tranche of \$5.0 million only becomes available to us if a pre-defined financing event occurs prior to March 31, 2012. We expect that these sources of cash should fund our operations and working capital requirements for the next 12 months, based on current operating plans. In addition to the PPD cash contribution and borrowings under the loan agreement, we expect to receive future milestone and royalty payments from our existing collaborations that would provide additional support for our operations and working capital requirements.

The timing and amount of any future expenses, trial completion dates and revenues related to our compounds are subject to significant uncertainty. We do not know if we will be successful in developing any of our drug candidates. The timing and amount of our research and development expenses will depend upon the costs associated with the present and potential future clinical trials and non-clinical studies of our drug candidates, any related expansion of our research and development organization, regulatory requirements and manufacturing costs. There are numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of events arising during clinical development. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those we currently anticipate to complete clinical development of a drug candidate, or if we experience significant delays in enrollment in any of our clinical trials, we would be required to expend significant additional financial resources and time on the completion of clinical development. The timing and amount of revenues, if any, are dependent upon the success of the clinical trials as well as the commercial success of these products in the marketplace, all of which are subject to a variety of risks and uncertainties.

Our future capital requirements will depend on numerous factors, including, among others: the cost and expense of continuing the research and development activities of our existing candidates; new collaborative agreements that we might enter into in the future; progress of product candidates in clinical trials as it relates to the cost of development and the receipt of future milestone payments, if any; the ability of our licensees and collaborators to obtain regulatory approval and successfully manufacture and market licensed products; the continued or additional support by our collaborators or other third parties of R&D efforts and clinical trials; time required to gain regulatory approvals; the demand for our potential products, if and when approved; potential acquisitions of technology, product candidates or businesses by us; and the costs of defending or prosecuting any patent opposition or litigation necessary to protect our proprietary technologies. In order to develop and obtain regulatory approval for our potential product candidates we might need to raise additional funds through equity or debt financings or from other sources, collaborative arrangements, the use of sponsored research efforts or other means. Additional financing might not be available on acceptable terms, if at all, and such financing might only be available on terms dilutive or otherwise detrimental to our stockholders or our business.

For the year ended December 31, 2011, our operating activities used \$49.0 million in cash as compared to \$43.3 million used for the same period in 2010. The increase in net cash used in operating activities of \$5.7 million was due primarily to changes in operating assets and liabilities, a decrease in revenue of \$4.5 million and a decrease in R&D expenses of \$5.9 million from 2010, and discontinued operations of \$5.1 million in 2010.

For the year ended December 31, 2011, our investing activities used \$10.0 million in cash related to the purchase of short-term investments. For the year ended December 31, 2010, our investing activities provided \$2.8 million in cash. The purchaser of Piedmont Research Center, LLC had an indemnification holdback of \$3.5 million, which PPD received, offset by purchases of property and equipment of \$0.7 million.

For the year ended December 31, 2011, our financing activities provided \$10.0 million in cash under the loan agreement with MidCap Funding III, LLC and Silicon Valley Bank and \$0.6 million from the issuance of common stock related to option exercises by employees and consultants. For the year ended December 31, 2010, our financing activities provided \$22.6 million of cash related to the net change in investment from our former parent and \$100.0 million related to cash contributed by PPD as part of the spin-off.

As of December 31, 2011, we had three collaborations that involve potential future expenditures. The first is our collaboration with Alza for Priligy. In connection with this collaboration, we have an obligation to pay a royalty to Eli Lilly and Company of 5% on annual net sales of the compound in excess of \$800.0 million. As of December 31, 2011, we are not obligated to pay any ongoing costs of development for this compound. We are actively evaluating and pursuing the possibility of restructuring the existing agreement with Alza, for Priligy, with the possibility of involving another collaborative partner. Any transaction might require that the Company negotiate additional out-licenses or collaborations, and could require additional external sources of financing.

The second collaboration involving future expenditures is in respect of the two compounds in-licensed from Janssen: JNJ-Q2 and MuDelta. On April 18, 2011, Janssen announced that in connection with a broad strategic review of its portfolio of infectious disease programs, it will be redirecting its research and development efforts toward antivirals and vaccines, and will not be investing in the development of new antibacterial therapies. As a result, Janssen elected not to exercise its option to continue the development of the JNJ-Q2 compound. On April 19, 2011, we announced we had acquired full exclusive license rights to develop and commercialize the JNJ-Q2 compound under our existing development and license agreement with Janssen. On November 1, 2011, we announced we had acquired full exclusive license rights to develop and commercialize the MuDelta compound under our existing development and license agreement with Janssen. We acquired these rights as a result of Janssen's decision not to exercise its option under the agreement to continue development of JNJ-Q2 and MuDelta.

We plan to continue evaluating other partnering and funding opportunities for both the JNJ-Q2 and MuDelta compounds. We may be obligated to pay Janssen, for both the JNJ-Q2 and MuDelta compounds, individually, up to \$50.0 million in regulatory milestone payments and, if approved for marketing, up to \$75.0 million in sales-based milestone payments and sales-based royalties increasing from the mid- to upper-single digit percentages as sales volume increases. Royalties would be paid for a period of ten years after the first commercial sale or, if later, the expiration of the last valid patent claim or the expiration of patent exclusivity.

We currently expect expenses associated with the continued development of MuDelta to be between \$30.0 and \$35.0 million over the next year related to Phase III costs.

The third collaboration involving future expenditures is with Ranbaxy for a statin compound, PPD-10558. In December 2011, we announced top-line results from the Phase II trial of PPD-10558. Based on these results, we have discontinued further spending on the PPD-10558 program and plan to terminate our license agreement with Ranbaxy in accordance with the terms of the agreement. We will owe Ranbaxy a \$1.0 million development milestone payment upon completion of the Phase II final study report, which is expected to occur in the second quarter of 2012.

If required, we might seek funds from new collaborators or from issuances of equity or debt securities or from other sources.

While we believe we will have adequate sources of liquidity to fund our operations for at least 12 months, our sources of liquidity over that time period could be affected by among other things: risks and costs related to our development efforts, regulatory approval and commercialization of our product candidates; changes in regulatory compliance requirements; reliance on existing collaborators and the potential need to enter into additional collaborative arrangements; personal injury or other tort claims; international risks; environmental or intellectual property claims; or other factors described under "Item 1A. Risk Factors."

Contractual Obligations

On August 18, 2011, we entered into a Loan and Security Agreement with MidCap Funding III, LLC and Silicon Valley Bank, collectively, the Lenders. The loans are divided into two separate tranches. The first tranche of \$10.0 million closed on August 18, 2011. The second tranche of \$5.0 million only becomes available to us if a pre-defined financing event occurs prior to March 31, 2012. The first tranche bears interest at a fixed rate of 10.25% per annum and is due August 1, 2015. Interest accrues monthly and is payable on the first day of the following month, in arrears. Principal payments of the first tranche begin on August 1, 2012, are due the first day of each month, and will be paid on a ratable monthly basis until maturity. We intend to use the proceeds from the loans to support research and development for our clinical stage compounds JNJ-Q2 and MuDelta.

A final payment fee is due to the Lenders in an amount equal to 2.5% of the loan commitments, payable at the maturity date or earlier prepayment of the loans. We may prepay the first tranche subject to a prepayment fee of between one and four percent of the amount borrowed, depending on the time of the prepayment. The amount of interest expense related to the Loan Agreement included in the statements of operations for the year ended December 31, 2011 was \$0.4 million. Included in this amount is the ratable accrual over the term of the loan of the final payment fee, payable upon the maturity date, which is presented in other long-term liabilities within the consolidated balance sheets.

Under the Loan Agreement, we are subject to affirmative covenants customary for financings of this type, including the obligations to maintain good standing, provide certain notices to the Lenders, deliver financial statements to the Lenders, maintain insurance, discharge all taxes, protect intellectual property and protect collateral. We are also subject to negative covenants customary for financings of this type, including that we may not enter into a merger or consolidation or certain change of control events, incur liens on the collateral, incur additional indebtedness, dispose of any property, change our jurisdictions of organization or our organizational structures or types, declare or pay dividends (other than dividends payable solely in common stock), make certain investments or acquisitions, and enter into certain transactions with affiliates, in each case subject to certain customary exceptions, including exceptions that allow us to acquire additional compounds and to enter into licenses and similar agreements providing for the use and collaboration of our intellectual property provided certain conditions are met. Our cash, cash equivalents and short-term investment accounts serve as collateral for the loan. We are currently in compliance with our obligations under the Agreement.

The Loan Agreement provides that events of default include failure to make payment of principal or interest on the loan when required, failure to perform certain obligations under the Loan Agreement and related documents, defaults in certain other indebtedness and certain other events including certain adverse actions taken by the Food and Drug Administration or other governmental authorities. Upon events of default, our obligations under the Loan Agreement may, or in the event of insolvency or bankruptcy will automatically, be accelerated. Upon the occurrence of any event of default, our obligations under the Loan Agreement will bear interest at a rate equal to the lesser of (a) 4% above the rate of interest applicable to such obligations immediately prior to the occurrence of the event of default and (b) the maximum rate allowable under law.

As of December 31, 2011, future minimum payments on all our contractual obligations for years subsequent to December 31, 2011 were as follows related to our Loan Agreement and operating leases in the following locations: Morrisville, North Carolina; Wilmington, North Carolina; Rockville, Maryland; Richmond, Virginia; Blue Bell, Pennsylvania; and Austin, Texas:

Years Ended December 31 (in thousands)	2012	2013	2014	2015	Total
Long-term Debt: Principal	\$1,351	\$3,243	\$3,243	\$2,163	\$10,000
Long-term Debt: Interest	1,069	778	441	101	2,389
Operating Leases	115	38	—	—	153
Total Contractual Obligations	<u>\$2,535</u>	<u>\$4,059</u>	<u>\$3,684</u>	<u>\$2,264</u>	<u>\$12,542</u>

As of December 31, 2011, we were contingently obligated under collaboration agreements that have not been included in the table above due to the inherent uncertainty in the amounts and timing of payments. For more information, see "Liquidity and Capital Resources."

Off-balance Sheet Arrangements

We have no off-balance sheet arrangements except for operating leases entered into in the normal course of business.

Critical Accounting Policies and the Use of Estimates

The preparation of our combined and consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in our combined and consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates. The items in our combined and consolidated financial statements requiring significant estimates and judgments are as follows:

Revenue Recognition

We generate revenue in the form of upfront payments, development and regulatory milestone payments, royalties and sales-based milestone payments in connection with the out-licensing of compounds. The payment of future milestones and royalties will depend on the success of our compound development and our collaborators' success in developing and commercializing compounds. Upfront payments are generally paid within a short period of time following the execution of an out-license or collaboration agreement. Milestone payments are typically one-time payments to us triggered by our collaborator's achievement of specified development and regulatory events such as the commencement of Phase III trials or regulatory submission approval. Royalties are payments received by us based on net product sales of a collaborator. Sales-based milestone payments are typically one-time payments to us triggered when aggregate net sales of product by a collaborator for a specified period (for example, an annual period) reach an agreed upon threshold amount. We recognize upfront payments, development and regulatory milestone payments, royalty payments and sales-based milestone payments from our collaborators when the event which triggers the obligation of payment has occurred, there is no further obligation on our part in connection with the payment and collection is reasonably assured.

Goodwill

We review goodwill for impairment annually on October 1 and whenever events or changes in circumstances indicate that the carrying amount of an asset might not be recoverable. In performing the annual impairment test, the fair value of the Company was determined using the income approach. We have a single reporting unit. For purposes of the income approach, fair value was determined based on the present value of estimated future cash flows, discounted at an appropriate risk-adjusted rate. We made assumptions about the amount and timing of future expected cash flows, probability of future compound development and appropriate discount rates. The compound development estimates are highly subjective due to the uncertainty associated with the amounts and timing of expected milestone and royalty payments. The amount and timing of future cash flows within our analysis are based on our most recent operational budgets, long range strategic plans and other estimates. Actual results may differ from those assumed in our forecasts, which could have a material impact on our combined and consolidated financial statements. We use estimates of market participant weighted average cost of capital as a basis for determining the discount rates to apply to our future expected cash flows, adjusted for the risks and uncertainty inherent in our industry generally and in our internally developed forecasts. Based on our review as of October 1, 2011, our calculated fair value of equity was in excess of carrying value by a substantial margin.

The fair value of goodwill could be materially impacted by future adverse changes such as future declines in operating results, a decline in the valuation of pharmaceutical and biotechnology company stocks, including the valuation of our own common stock, a slowdown in the worldwide economy or the pharmaceutical and biotechnology industry, failure to meet the performance projections included in our forecasted operating results or the delay or abandonment of any research and development programs.

Share-Based Compensation

We recognize compensation expense using a fair-value based method related to stock options and other share-based compensation. The expense is measured based on the grant date fair value of the awards that are expected to vest and is recorded over the applicable requisite service period. In the absence of an observable market price for a share-based award, the fair value is based upon a valuation methodology that takes into consideration various factors, including the exercise price of the award, the expected term of the award, the current price of the underlying shares, the expected volatility of the underlying share price based on peer companies, the expected dividends on the underlying shares and the risk-free interest rate. A change in the assumptions used in the fair-value based calculation could have a significant impact on the fair value of options. See Note 9 to our combined and consolidated financial statements for details regarding the assumptions used in estimating fair value for the years ended December 31, 2009, 2010 and 2011 regarding equity awards granted to Furiex employees by PPD and Furiex.

Tax Valuation Allowances

We calculated our income tax provision for the periods prior to June 14, 2010 using the separate return basis as if we had filed separate income tax returns under our existing structure. The provision for income taxes subsequent to the spin-off has been determined using the asset and liability approach of accounting for income taxes. Under this approach, deferred taxes represent the future tax consequences expected to occur when the reported amounts of assets and liabilities are recovered or paid. The provision for income taxes represents income taxes paid or payable for the year, plus the change in deferred taxes during the year. Deferred taxes result from differences between the financial reporting and tax basis of our assets and liabilities. Deferred tax assets and liabilities are measured using the currently enacted tax rates that apply to taxable income in effect for the years in which those tax attributes are expected to be recovered or paid, and are adjusted for changes in tax rates and tax laws when changes are enacted.

Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized. The assessment of whether or not a valuation allowance is required often requires significant judgment, including the long-range forecast of future taxable income and the evaluation of tax planning initiatives. Adjustments to the deferred tax valuation allowances are made to earnings in the period when such assessments are made. Due to the historical losses from our operations, a full valuation allowance on deferred tax assets has been recorded.

For the year ended December 31, 2011, we recorded an insignificant amount of income tax expense. This amount relates to the adjustment of a deferred tax liability associated with historical goodwill, which is amortized and deductible for tax purposes, but is an indefinite-lived intangible asset for financial reporting purposes. The amount reflected in the statements of operations for year ended December 31, 2011 is the tax effect of the tax amortization of this item. Because the associated deferred tax liability relates to an indefinite-lived intangible, we do not consider this item in computing the valuation allowance related to our net deferred tax assets. As of December 31, 2011, the deferred tax liability associated with this intangible asset, reflected in other long-term liabilities within the consolidated balance sheets, was approximately \$0.2 million.

Recent Accounting Pronouncements

In October 2009, the Financial Accounting Standards Board, or FASB, issued a new accounting standard related to the accounting for revenue arrangements with multiple deliverables. This standard applies to all

deliverables in contractual arrangements in all industries in which a vendor will perform multiple revenue-generating activities. This standard also addresses the unit of accounting for an arrangement involving multiple deliverables and how arrangement consideration should be allocated. Our adoption of this standard on January 1, 2011 did not have a material impact on our combined and consolidated financial statements.

In March 2010, the FASB issued a new accounting standard, the objective of which is to establish a revenue recognition model for contingent consideration that is payable upon the achievement of an uncertain future event, referred to as a milestone. Our adoption of this standard on January 1, 2011 did not have a material impact on our combined and consolidated financial statements.

In September 2011, the FASB issued an update to the accounting standard that permits an entity to make a qualitative assessment of whether it is more likely than not that a reporting unit's fair value is less than its carrying value before applying the two-step goodwill impairment model that is currently required. If it is determined through the qualitative assessment that a reporting unit's fair value is, more likely than not, greater than its carrying value, the remaining impairment steps would be unnecessary. The qualitative assessment is optional, allowing companies to proceed directly to the quantitative assessment. This update is effective for annual and interim goodwill impairment tests performed in fiscal years beginning after December 15, 2011; however, early adoption is permitted. We did not early adopt this standard and are currently evaluating the impact this update will have on our combined and consolidated financial statements.

Income Taxes

Except for the pre-acquisition federal and state tax filings for Magen BioSciences, Inc. and certain separate state filings through the June 14, 2010 spin-off, our operations have been included in the consolidated federal and combined state tax returns of PPD. As such, except for the pre-acquisition tax attributes of Magen BioSciences, Inc., and some losses from certain separate filing states, the tax attributes of our operations prior to June 14, 2010 have been utilized or paid by PPD. Thus, the tax attributes which have been included in PPD's combined returns have not been accounted for in the results of our operations. Subsequent to June 14, 2010, we have filed federal and state returns separately from PPD and can use our tax attributes accordingly.

Potential Volatility of Annual Operating Results

Our annual operating results have fluctuated in the past, and we expect that they will continue to fluctuate in the future. Factors that could cause these fluctuations to occur include:

- the success of achieving milestones and the timing of our milestone payments or other revenue, if any;
- our dependence on a small number of compounds and collaborations;
- the success or failure of clinical trials and other aspects of developing and commercializing our product candidates;
- our ability to properly manage our growth;
- the timing and amount of costs associated with R&D and compound partnering collaborations;
- our ability to recruit and retain experienced personnel;
- the timing and extent of new government regulations; and
- intellectual property risks.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Under our current investment policies, we invest our cash and cash equivalents and short-term investments in money market funds which invest in short-term U.S. Treasury securities with insignificant rates of return. Due to the short-term nature of our investments, we do not believe that a decrease in market rates would have a significant negative impact on the value of our cash and cash equivalents and short-term investments.

Under our Loan and Security Agreement with MidCap Funding III, LLC and Silicon Valley Bank, we borrowed \$10.0 million on August 18, 2011. This outstanding debt bears interest at a fixed rate of 10.25% per annum and is due August 1, 2015. Due to the fixed rate associated with this outstanding debt, an increase in market rates would have no impact on our future obligations as of December 31, 2011.

Our purchases of raw materials and finished goods are denominated primarily in U.S. dollars, purchases denominated in currencies other than the U.S. dollar are insignificant. Additionally, our net assets denominated in currencies other than the U.S. dollar are insignificant and have not historically exposed us to material risk associated with fluctuations in currency rates.

Given these facts, we have not considered it necessary to use foreign currency contracts or other derivative instruments to manage changes in currency rates. We do not now, nor do we plan to, use derivative financial instruments for speculative or trading purposes. However, these circumstances might change.

Item 8. Financial Statements and Supplementary Data

The information required by this Item is set forth in the Combined and Consolidated Financial Statements and Notes thereto beginning at page F-1 of this Report.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) are designed only to provide reasonable assurance that information to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our President and Chief Medical Officer (our principal executive officer) and our Chief Financial Officer, Treasurer and Assistant Secretary (our principal financial and accounting officer), of the effectiveness of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, our President and Chief Medical Officer and our Chief Financial Officer, Treasurer and Assistant Secretary have concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report to provide the reasonable assurance discussed above.

Internal Control Over Financial Reporting

No change to our internal control over financial reporting occurred during the last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining effective internal control over financial reporting as defined in Rules 13a-15(f) under the Securities Exchange Act of 1934. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our

receipts and expenditures are being made only in accordance with authorizations of management and our Board of Directors and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

A control system, no matter how well designed and operated, can only provide reasonable, not absolute, assurance that the objectives of the control system are met and must reflect the fact that there are resource constraints that require management to consider the benefits of internal controls relative to their costs. Because of these inherent limitations, management does not expect that our internal controls over financial reporting will prevent all errors and all fraud. Also, internal controls might become inadequate because of changes in business conditions or a decline in the degree of compliance with our policies or procedures.

Management, with the participation of our President and Chief Medical Officer and our Chief Financial Officer, Treasurer and Assistant Secretary, assessed the effectiveness of our internal control over financial reporting as of December 31, 2011. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control—Integrated Framework*. Based on our assessment, we believe that, as of December 31, 2011, our internal control over financial reporting was effective based on those criteria.

Deloitte & Touche, LLP, the registered public accounting firm that audited the financial statements included in this annual report, has also issued an opinion on our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of
Furiex Pharmaceuticals, Inc.
Morrisville, North Carolina

We have audited the internal control over financial reporting of Furiex Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2011, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements as of and for the year ended December 31, 2011, of the Company and our report dated March 7, 2012, expressed an unqualified opinion on those financial statements.

/s/ DELOITTE & TOUCHE LLP
Raleigh, North Carolina

March 7, 2012

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information required by this Item concerning our directors is incorporated by reference from the section captioned “Proposal No. 1—Election of Directors” contained in our proxy statement related to the 2012 Annual Meeting of Stockholders scheduled to be held on May 24, 2012 which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

The Board of Directors has determined that the members of the Audit Committee are independent as defined in Rule 4200(a)(15) of the National Association of Securities Dealers’ listing standards. The Board of Directors has also determined that Committee Chair Robert P. Ruscher is an “audit committee financial expert” as defined in Item 401(h) of Regulation S-K.

Our Board of Directors adopted a code of conduct that applies to all of our directors and employees. Our Board also adopted a separate code of ethics for our President (principal executive officer), Chief Financial Officer and Treasurer (principal financial and accounting officer), and Corporate Controller, or persons performing similar functions. We will provide copies of our code of conduct and code of ethics without charge upon request. To obtain a copy of our code of conduct and code of ethics, please send your written request to Furiex Pharmaceuticals, Inc., 3900 Paramount Parkway, Suite 150, Morrisville, North Carolina 27560, Attn: Investor Relations. In addition, you can find those codes on our website at <http://www.furiex.com/investors/corporate-governance/>.

The information required by this Item concerning executive officers of the Registrant is set forth at the end of Part I of this report.

The information required by this Item concerning compliance with Section 16(a) of the United States Securities Exchange Act of 1934, as amended, is incorporated by reference from the section of the proxy statement captioned “—Section 16(a) Beneficial Ownership Reporting Compliance.”

Item 11. Executive Compensation

The information required by this Item is incorporated by reference to the information under the sections captioned “—Compensation for Non-Employee Directors,” “—Compensation Discussion and Analysis,” “—Summary Compensation Table,” “—Grants of Plan Based Awards in Fiscal 2011,” “—Outstanding Equity Awards at Fiscal Year-End 2011,” “—Compensation Committee Report,” and “—Compensation Committee Interlocks and Insider Participation” contained in the proxy statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Equity Compensation Plans

The following table sets forth the indicated information as of December 31, 2011 with respect to our equity compensation plans:

<u>Plan Category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights</u>	<u>Weighted-average exercise price of outstanding options, warrants and rights</u>	<u>Number of securities remaining available for future issuance under equity compensation plans</u>
Equity compensation plans approved by our shareholders	1,511,224	\$11.45	199,335
Equity compensation plans not approved by our shareholders	—	—	—
Total	1,511,224	\$11.45	199,335

Our equity compensation plan consists of the 2010 Stock Plan, which was approved by our stockholders. We do not have any equity compensation plans or arrangements that have not been approved by our stockholders.

The other information required by this Item is incorporated by reference to the information under the section captioned “—Security Ownership of Management and Certain Beneficial Owners” contained in the proxy statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item is incorporated by reference to the information under the section captioned “—Related Party Transactions” and “Proposal No. 1—Election of Directors—Information About the Board of Directors and its Committees” contained in the proxy statement.

Item 14. Principal Accounting Fees and Services

The information required by this Item is incorporated by reference to the information under the section captioned “—Report of the Audit Committee” and “—Fees Paid to the Independent Registered Public Accounting Firm” contained in the proxy statement.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) Financial Statements

Our combined and consolidated financial statements filed as part of this report are listed in the attached Index to Combined and Consolidated Financial Statements. There are no schedules to our combined and consolidated financial statements.

(b) Exhibits

<u>Exhibit No.</u>	<u>Exhibit Description</u>	<u>Registrant's Form</u>	<u>Dated</u>	<u>Exhibit Number</u>	<u>Filed Herewith</u>
2.1	Separation and Distribution Agreement by and between Furiex Pharmaceuticals, Inc. and Pharmaceutical Product Development, Inc.	8-K	6/18/10	2.1	
3.1	Amended and Restated Certificate of Incorporation.	10-12B	2/24/10	3.1	
3.2	Amended and Restated Bylaws.	10-12B	2/24/10	3.2	
10.1	Sublease Agreement dated as of June 14, 2010 by and between Furiex Pharmaceuticals, Inc. and PPD Development, LP.	8-K	6/18/10	10.2	
10.2	Tax Sharing Agreement dated as of June 14, 2010 by and between Furiex Pharmaceuticals, Inc. and Pharmaceutical Product Development, Inc.	8-K	6/18/10	10.3	
10.3	Employee Matters Agreement dated as of June 14, 2010 by and between Furiex Pharmaceuticals, Inc. and Pharmaceutical Product Development, Inc.	8-K	6/18/10	10.4	
10.4	Transition Services Agreement dated as of June 14, 2010 by and between Furiex Pharmaceuticals, Inc. and Pharmaceutical Product Development, Inc.	8-K	6/18/10	10.5	
10.5†	Master Development Services Agreement dated as of June 14, 2010 by and between Furiex Pharmaceuticals, Inc. and PPD Development, LP.	8-K	6/18/10	10.6	
10.6†	MuDelta Development and License Agreement dated as of November 16, 2009 by and between Janssen Pharmaceutica, N.V. and PPD Therapeutics, Inc., as amended February 9, 2010.	10-12B/A	5/14/10	10.6	
10.7†	MuDelta Master Services Agreement dated as of November 16, 2009 by and between Janssen Pharmaceutica, N.V. and PPD Therapeutics, Inc.	10-12B	2/24/10	10.7	
10.8†	Topo Development and License Agreement, dated as of November 16, 2009 by and between Janssen Pharmaceutica, N.V. and PPD Therapeutics, Inc., as amended February 15, 2010.	10-12B/A	5/14/10	10.8	

<u>Exhibit No.</u>	<u>Exhibit Description</u>	<u>Registrant's Form</u>	<u>Dated</u>	<u>Exhibit Number</u>	<u>Filed Herewith</u>
10.9†	Topo Master Services Agreement dated as of November 16, 2009 by and between Janssen Pharmaceutica, N.V. and PPD Therapeutics, Inc.	10-12B	2/24/10	10.9	
10.10†	License Agreement dated as of January 2, 2001 by and among Pharmaceutical Product Development, Inc., GenuPro, Inc. and Alza Corporation, as amended December 26, 2003 and October 16, 2009.	10-12B/A	5/25/10	10.10	
10.11†	Agreement between Takeda San Diego, Inc., Takeda Pharmaceutical Company Limited, Development Partners LLC, and Pharmaceutical Product Development, Inc., dated as of July 13, 2005, as amended October 10, 2005.	10-12B/A	5/27/10	10.11	
10.12†	Termination and License Agreement dated as of December 18, 2003 by and among Eli Lilly and Company, Pharmaceutical Product Development, Inc., GenuPro, Inc. and APBI Holdings, LLC.	10-12B	2/24/10	10.12	
10.13†	Option and License Agreement effective as of December 15, 2006 among Pharmaco Investments, Inc. and Ranbaxy Laboratories Ltd.	10-12B/A	5/25/10	10.13	
10.16	Employment Agreement effective as of March 16, 2010 between Furiex Pharmaceuticals, Inc. and June S. Almenoff, M.D. Ph.D.	10-12B/A	5/14/10	10.16	
10.17	Employment Agreement effective as of April 1, 2010 between Furiex Pharmaceuticals, Inc. and Gail McIntyre.	10-12B/A	5/14/10	10.17	
10.18	Employment Agreement effective as of January 15, 2010 between Furiex Pharmaceuticals, Inc. and Paul S. Covington, M.D.	10-12B/A	5/14/10	10.18	
10.19	Employment Agreement effective as of January 29, 2010 between Furiex Pharmaceuticals, Inc. and Marshall Woodworth.	10-12B/A	5/14/10	10.19	
10.20	Form of Severance Agreement between Furiex Pharmaceuticals, Inc. and various individuals.	10-12B	2/24/10	10.20	
10.21	2010 Stock Plan.	10-12B	2/24/10	10.21	
10.22	Consulting Agreement by and between Furiex Pharmaceuticals, Inc., Elk Mountain Consulting, LLC, and Fredric N. Eshelman.	8-K	6/18/10	10.7	
10.23†	Loan and Security Agreement dated August 18, 2011 with Midcap Funding III, LLC and Silicon Valley Bank (the Lenders).	10-Q	11/10/11	10.23	
10.24	Pledge Agreement dated August 18, 2011 with the Lenders.	10-Q	11/10/11	10.24	

<u>Exhibit No.</u>	<u>Exhibit Description</u>	<u>Registrant's Form</u>	<u>Dated</u>	<u>Exhibit Number</u>	<u>Filed Herewith</u>
10.25	Secured Promissory Note dated August 18, 2011 to the Lenders.	10-Q	11/10/11	10.25	
21.1	Subsidiaries of Furiex Pharmaceuticals, Inc.				X
23.1	Consent of Independent Registered Public Accounting Firm.				X
31.1	Certification by the principal executive officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification by the principal financial officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certification by the principal executive officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2	Certification by the principal financial officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101	Financial information from the Company's Annual Report on Form 10-K for the period ended December 31, 2011 formatted in eXtensible Business Reporting Language (XBRL).				X

† Confidential treatment requested for portions of this exhibit.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

FURIEX PHARMACEUTICALS, INC.

Date: March 7, 2012

By: /s/ JUNE S. ALMENOFF
 Name: **June S. Almenoff**
 Title: **President**
 (Principal Executive Officer)

By: /s/ MARSHALL H. WOODWORTH
 Name: **Marshall H. Woodworth**
 Title: **Chief Financial Officer**
 (Principal Financial Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u> /s/ JUNE S. ALMENOFF </u> June S. Almenoff	President (Principal Executive Officer)	March 7, 2012
<u> /s/ MARSHALL H. WOODWORTH </u> Marshall H. Woodworth	Chief Financial Officer (Principal Financial and Accounting Officer)	March 7, 2012
<u> /s/ FREDRIC N. ESHELMAN </u> Fredric N. Eshelman	Chairman	March 7, 2012
<u> /s/ STUART BONDURANT </u> Stuart Bondurant	Director	March 7, 2012
<u> /s/ PETER B. CORR </u> Peter B. Corr	Director	March 7, 2012
<u> /s/ WENDY L. DIXON </u> Wendy L. Dixon	Director	March 7, 2012
<u> /s/ STEPHEN W. KALDOR </u> Stephen W. Kaldor	Director	March 7, 2012
<u> /s/ ROBERT P. RUSCHER </u> Robert P. Ruscher	Director	March 7, 2012

FURIEX PHARMACEUTICALS, INC. AND SUBSIDIARIES
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of
Furiex Pharmaceuticals, Inc.
Morrisville, North Carolina

We have audited the accompanying consolidated balance sheets of Furiex Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2010 and 2011, and the related combined and consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2011. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such combined and consolidated financial statements present fairly, in all material respects, the financial position of Furiex Pharmaceuticals, Inc. and subsidiaries as of December 31, 2010 and 2011, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2011, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2011, based on the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 7, 2012 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP
Raleigh, North Carolina

March 7, 2012

FURIEX PHARMACEUTICALS, INC. AND SUBSIDIARIES
COMBINED AND CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED DECEMBER 31, 2009, 2010 AND 2011
(in thousands)

	<u>2009</u>	<u>2010</u>	<u>2011</u>
Revenue:			
Milestones	\$ 5,000	\$ 7,500	\$ —
Royalties	923	1,330	4,490
Service	389	75	—
Other	—	78	—
Total revenue	<u>6,312</u>	<u>8,983</u>	<u>4,490</u>
Direct expenses	265	21	—
Research and development expenses (Note 14)	11,795	50,112	44,202
Selling, general and administrative expenses	2,551	8,262	8,761
Depreciation and amortization	10	109	83
Total operating expenses	<u>14,621</u>	<u>58,504</u>	<u>53,046</u>
Operating loss	(8,309)	(49,521)	(48,556)
Interest expense	—	—	413
Other income, net	10	9	2
Loss from continuing operations before provision for income taxes	(8,299)	(49,512)	(48,967)
Provision for income taxes	—	14	14
Loss from continuing operations	(8,299)	(49,526)	(48,981)
Loss from discontinued operations, net of income taxes	(632)	(5,133)	—
Net loss	<u>\$ (8,931)</u>	<u>\$ (54,659)</u>	<u>\$ (48,981)</u>
Loss from continuing operations per basic and diluted share	<u>\$ (0.84)</u>	<u>\$ (5.01)</u>	<u>\$ (4.96)</u>
Loss from discontinued operations, net of income taxes per basic and diluted share	<u>\$ (0.06)</u>	<u>\$ (0.52)</u>	<u>\$ —</u>
Net loss per basic and diluted share	<u>\$ (0.90)</u>	<u>\$ (5.53)</u>	<u>\$ (4.96)</u>
Weighted-average shares used to compute net loss per basic and diluted share ⁽¹⁾ :	9,881	9,881	9,884

(1) See discussion of share computation at Note 1.

The accompanying notes are an integral part of these combined and consolidated financial statements.

FURIEX PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

AS OF DECEMBER 31, 2010 AND 2011

(in thousands)

	<u>December 31,</u> <u>2010</u>	<u>December 31,</u> <u>2011</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 82,030	\$ 33,628
Short-term investments	—	10,000
Accounts receivable, net	259	1,985
Prepaid expenses	226	214
Other current assets	740	—
Total current assets	<u>83,255</u>	<u>45,827</u>
Property and equipment, net	188	181
Goodwill	<u>49,116</u>	<u>49,116</u>
Total assets	<u>\$132,559</u>	<u>\$ 95,124</u>
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 96	\$ 147
Accrued expenses	13,767	10,422
Current portion of long-term debt	—	1,351
Total current liabilities	<u>13,863</u>	<u>11,920</u>
Long-term debt, net	—	8,649
Other long-term liabilities	<u>192</u>	<u>232</u>
Total liabilities	<u>14,055</u>	<u>20,801</u>
Commitments and contingencies (Note 12)		
Common stock, \$0.001 par value, 40,000,000 shares authorized; 9,881,340 and 9,949,422 shares issued and outstanding, respectively	10	10
Preferred stock, \$0.001 par value, 10,000,000 shares authorized; No shares issued and outstanding, respectively	—	—
Paid-in capital	153,638	158,438
Accumulated deficit	<u>(35,144)</u>	<u>(84,125)</u>
Total shareholders' equity	<u>118,504</u>	<u>74,323</u>
Total liabilities and shareholders' equity	<u>\$132,559</u>	<u>\$ 95,124</u>

The accompanying notes are an integral part of these combined and consolidated financial statements.

FURIEX PHARMACEUTICALS, INC. AND SUBSIDIARIES
COMBINED AND CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2009, 2010 AND 2011
(in thousands)

	Common Stock		Paid-in capital	Accumulated deficit	Parent Company Investment	Total
	Shares	Par value				
Balance January 1, 2009	—	\$—	\$ —	\$ —	\$ 55,524	\$ 55,524
Net transfers from parent	—	—	—	—	2,677	2,677
Net loss	—	—	—	—	(8,931)	(8,931)
Balance December 31, 2009	—	\$—	\$ —	\$ —	\$ 49,270	\$ 49,270
Net transfers from parent	—	—	—	—	16,046	16,046
Net liability retained by parent	—	—	—	—	6,637	6,637
Stock compensation expense	—	—	1,210	—	—	1,210
Contribution of cash and cash equivalents from parent	—	—	—	—	100,000	100,000
Contribution of net operating assets and liabilities to Furiex Pharmaceuticals, Inc. and issuance of common shares to Pharmaceutical Product Development, Inc. shareholders	9,881	10	152,428	—	(152,438)	—
Net loss and comprehensive loss	—	—	—	(35,144)	(19,515)	(54,659)
Balance December 31, 2010	9,881	\$ 10	\$153,638	\$(35,144)	\$ —	\$118,504
Exercise of common stock options	68	—	620	—	—	620
Stock compensation expense	—	—	4,180	—	—	4,180
Net loss and comprehensive loss	—	—	—	(48,981)	—	(48,981)
Balance December 31, 2011	<u>9,949</u>	<u>\$ 10</u>	<u>\$158,438</u>	<u>\$(84,125)</u>	<u>\$ —</u>	<u>\$ 74,323</u>

The accompanying notes are an integral part of these combined and consolidated financial statements.

FURIEX PHARMACEUTICALS, INC. AND SUBSIDIARIES
COMBINED AND CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2009, 2010 AND 2011
(in thousands)

	<u>2009</u>	<u>2010</u>	<u>2011</u>
Cash flows from operating activities:			
Net loss	\$ (8,931)	\$ (54,659)	\$ (48,981)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,271	1,169	83
Impairment of intangible assets	10,361	—	—
Stock compensation expense	—	1,210	4,180
Net gain on sale of businesses	(26,707)	—	—
Loss on disposal of assets, net	7	—	—
Changes in operating assets and liabilities, net of acquisitions:			
Accounts receivable, net	377	302	(1,726)
Prepaid expenses and other current assets	506	1,038	752
Accounts payable	(1,050)	21	(3)
Accrued expenses	1,058	7,446	(3,345)
Deferred rent	(675)	(43)	—
Unearned income	(364)	—	—
Other long-term liabilities	—	192	40
Net cash used in operating activities	<u>(24,147)</u>	<u>(43,324)</u>	<u>(49,000)</u>
Cash flows from investing activities:			
Purchases of property and equipment	(512)	(683)	(22)
Purchases of short-term investments	—	—	(10,000)
Net proceeds from sale of businesses	40,267	3,464	—
Changes in restricted cash	(2,198)	—	—
Net cash paid for acquisition	<u>(11,729)</u>	<u>—</u>	<u>—</u>
Net cash provided by (used in) investing activities	<u>25,828</u>	<u>2,781</u>	<u>(10,022)</u>
Cash flows from financing activities:			
Proceeds from borrowing on long-term debt	—	—	10,000
Proceeds from issuance of common stock	—	—	620
Net change in investment from parent	(1,675)	22,567	—
Cash contributed by parent	—	100,000	—
Net cash (used in) provided by financing activities	<u>(1,675)</u>	<u>122,567</u>	<u>10,620</u>
Net increase (decrease) in cash and cash equivalents	6	82,024	(48,402)
Cash and cash equivalents, beginning of the year ⁽¹⁾	—	6	82,030
Cash and cash equivalents, end of the year	<u>\$ 6</u>	<u>\$ 82,030</u>	<u>\$ 33,628</u>
Supplemental Disclosure of Cash Flow Information:			
Interest paid	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 299</u>

(1) Cash and cash equivalents at December 31, 2009 related to discontinued operations. See Note 3.

The accompanying notes are an integral part of these combined and consolidated financial statements.

FURIEX PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2009, 2010 AND 2011
(dollars and shares in tables in thousands)

1. Summary of Operations and Significant Accounting Policies

Organization and Business Description

In October 2009, the Board of Directors of Pharmaceutical Product Development, Inc. (“PPD” or the “Parent Company”) authorized management of PPD to proceed with preparations to spin-off its compound partnering business, previously part of the discovery science segment of PPD, from its contract research organization business. In order to carry out the spin-off of the compound partnering business, PPD formed a new wholly-owned subsidiary, Furiex Pharmaceuticals, Inc., a Delaware corporation (“Furiex” or the “Company”), into which PPD transferred the compound partnering business, including assets, employees, intellectual property rights and liabilities comprising that business, and \$100.0 million in cash, as of the closing date of the spin-off, June 14, 2010. PPD effected the spin-off through a tax-free, pro-rata dividend distribution of all of the shares of the Company to PPD shareholders. PPD does not have any ownership or other form of equity interest in the Company following the spin-off.

In connection with the spin-off, the Company and PPD entered into a series of agreements, including a separation and distribution agreement, transition services agreement, sublease and license agreements, employee matters agreement, tax sharing agreement and a master development services agreement.

Furiex is a drug development company that continues the compound partnering business started by PPD in 1998. The goal of compound partnering is to in-license from, or form strategic alliances with, pharmaceutical and biotechnology companies to develop therapeutics in which the risks and rewards are shared. The Company’s operations are headquartered in Morrisville, North Carolina.

The Company has incurred losses and negative cash flows from operations since the spin-off. Based on current forecasts, the Company believes it has sufficient liquidity to continue its planned operations for the next 12 months. The Company’s long-term liquidity needs will largely be determined by the success of its products already in commercialization with collaborators, key development and regulatory events that may impact the Company’s ability to out-license its development compounds and the receipt of milestone payments related to various development activities. Depending upon the success and timing of receipt of various milestone payments and royalties it might be necessary to do one or more of the following in the future: (a) raise additional capital through equity or debt financings or from other sources; (b) reduce spending on one or more research and development programs; and (c) restructure the Company’s operations. The Company currently receives revenue from royalties on sales of Nesina® and Priligy®. The Company will continue to incur operating losses unless revenues from all sources reach a level sufficient to support its ongoing operations.

Basis of Accounting

The accompanying combined and consolidated financial statements, through the date of the spin-off from PPD, have been derived from the combined financial statements and accounting records of PPD from the historical cost basis of the assets and liabilities of the various activities that reflect the combined results of operations, financial condition and cash flows of the discovery sciences segment of PPD. All the business components of the discovery sciences segment have been included in the historical statements because they were managed by common segment management, and because they reflect the historical performance of PPD segment management.

FURIEX PHARMACEUTICALS, INC. AND SUBSIDIARIES
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(dollars and shares in tables in thousands)

PPD's net investment in the Company is shown in lieu of shareholders' equity in the combined financial statements prior to the spin-off as a direct ownership relationship did not exist among all the components comprising the Company. The net investment account represents the cumulative investments in, distributions from and earnings (loss) of the Company. Prior to the spin-off, all cash was held and managed by PPD. Accordingly, cash used to pay the Company's expenses or cash collected from collaboration agreements, royalties or customer contracts by PPD on behalf of the Company was recorded as an increase or decrease in PPD's net investment.

In 2009, PPD completed its disposition of Piedmont Research Center, LLC and PPD Biomarker Discovery Sciences, LLC, both of which were included in the discovery sciences segment of PPD. Due to the unique service offerings of these two subsidiaries, PPD determined these business units were no longer a long-term strategic fit and elected to sell them. In May 2010, PPD discontinued the operations of its wholly owned subsidiary, PPD Dermatology, Inc., due to unfavorable efficacy data associated with its MAG-131 program. These business units are recorded as discontinued operations in the accompanying combined and consolidated financial statements. As such, the accompanying financial information does not reflect the results of operations or cash flows of the Company had it been a separate, stand-alone entity during the periods presented prior to the spin-off. Additionally, the discovery sciences segment of PPD included pre-clinical consulting services that are not being offered by Furiex after the spin-off. All rights and obligations related to pre-clinical consulting services and the definitive purchase agreements related to Piedmont Research Center, LLC, PPD Biomarker Discovery Sciences, LLC and PPD Dermatology, Inc. were retained by PPD.

The Company was allocated expenses from PPD, such as executive oversight, risk management, accounting, tax, legal, investor relations, human resources, information technology, stock compensation, and facilities services and depreciation, but was not allocated the underlying productive assets, such as information systems equipment, furniture and facilities that were not assigned to the Company, but from which the Company benefited. Such expenses have been included in the combined and consolidated financial statements as expense allocations from PPD for periods prior to the spin-off. The basis of these allocations included full-time equivalent employees for the respective periods presented and square footage of occupied space. See Note 14 for further discussion of the allocations.

Management believes that the assumptions and allocations underlying the combined and consolidated financial statements are reasonable. However, the financial information in these combined and consolidated financial statements does not include all of the expenses that would have been incurred had the Company been a separate, stand-alone publicly traded entity prior to the spin-off.

Principles of Combination and Consolidation

The Company prepared the accompanying combined and consolidated financial statements in accordance with accounting principles generally accepted in the United States of America, or GAAP, and they include the accounts of Furiex Pharmaceuticals, Inc. and its subsidiaries. All intercompany balances and transactions have been eliminated in combination and consolidation.

Use of Estimates in Preparation of the Financial Statements

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

FURIEX PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2009, 2010 AND 2011
(dollars and shares in tables in thousands)

Earnings Per Share

The Company calculates net loss per basic and diluted share by dividing net loss by the weighted-average number of shares outstanding during the reporting period. The calculation of net loss per diluted share is the same as net loss per basic share since the inclusion of any potentially dilutive securities would be anti-dilutive for the year ended December 31, 2010 and 2011. For the year ended December 31, 2009, the calculation of net loss per diluted share is the same as net loss per basic share because there were no outstanding dilutive securities for that period. For all periods presented prior to the spin-off, the computation of net loss per basic and diluted share and the weighted-average shares outstanding are calculated based on the 9,881,340 shares issued in connection with the spin-off on June 14, 2010. All potentially dilutive securities relate to stock options issued as part of the Company's share-based compensation plan after the spin-off from PPD. Potentially dilutive securities totaling 839,000 and 1,511,000 options for 2010 and 2011, respectively, were excluded from the calculation of diluted loss per share because of their anti-dilutive effect.

Separation Costs

In 2010, the Company incurred legal, tax and other costs specifically associated with the spin-off, which are recorded as a component of selling, general and administrative expenses. These amounts for the year ended December 31, 2010 were \$2.6 million.

Revenue Recognition

The Company generates revenue in the form of upfront payments, development and regulatory milestone payments, royalties and sales-based milestone payments in connection with the out-licensing of compounds. The payment of future milestones and royalties will depend on the success of the Company's compound development and the Company's collaborators' success in developing and commercializing compounds. Upfront payments are generally paid within a short period of time following the execution of an out-license or collaboration agreement. Milestone payments are typically one-time payments to the Company triggered by the collaborator's achievement of specified development and regulatory events such as the commencement of Phase III trials or regulatory submission approval. Royalties are payments received by the Company based on net product sales of a collaborator. Sales-based milestone payments are typically one-time payments to the Company triggered when aggregate net sales of product by a collaborator for a specified period (for example, an annual period) reach an agreed upon threshold amount. The Company recognizes upfront payments, development and regulatory milestone payments, royalty payments and sales-based milestone payments from its collaborators when the event which triggers the obligation of payment has occurred, there is no further obligation on the Company's part in connection with the payment and collection is reasonably assured.

Concentration of Credit Risk

The Company's collaborators, which are its current sources of revenue, are primarily pharmaceutical companies. A concentration of credit risk with respect to revenue exists due to the small number of collaborators. Two collaborators accounted for the majority of the Company's revenue for the years ended December 31, 2010 and 2011. The December 31, 2010 and 2011 balance of accounts receivable relate entirely to royalty receivables related to Priligy and Nesina based on net product sales by the Company's collaborators. Based on its assessment of collection risks, the Company did not record a provision for doubtful accounts as of December 31, 2010 and 2011.

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NOTES TO COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
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Research and Development Expenses

Research and development costs consist primarily of costs associated with pre-clinical studies, non-clinical studies and the clinical trials of the Company's product candidates, development materials, patent costs, labor and related benefit charges associated with personnel performing research and development work, supplies associated with this work and consulting services. Research and development costs include clinical research services provided by PPD, pre-clinical testing, non-clinical testing and clinical drug manufacturing provided by third parties, the direct cost of the Company's personnel managing the programs and upfront and milestone payments to the Company's collaborators. The Company charges research and development costs to operations as incurred and discloses them in the combined and consolidated statements of operations.

Income Taxes

The Company calculated its income tax provision for the periods prior to June 14, 2010 using the separate return basis as if the Company had filed separate income tax returns under its existing structure. The provision for income taxes subsequent to the spin-off has been determined using the asset and liability approach of accounting for income taxes. Under this approach, deferred taxes represent the future tax consequences expected to occur when the reported amounts of assets and liabilities are recovered or paid. The provision for income taxes represents income taxes paid or payable for the year, plus the change in deferred taxes during the year. Deferred taxes result from differences between the financial reporting and tax basis of the Company's assets and liabilities. Deferred tax assets and liabilities are measured using the currently enacted tax rates that apply to taxable income in effect for the years in which those tax attributes are expected to be recovered or paid, and are adjusted for changes in tax rates and tax laws when changes are enacted.

Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized. The assessment of whether or not a valuation allowance is required often requires significant judgment, including the long-range forecast of future taxable income and the evaluation of tax planning initiatives. Adjustments to the deferred tax valuation allowances are made to earnings in the period when such assessments are made. Due to the historical losses from the Company's operations, a full valuation allowance on deferred tax assets has been recorded.

Share-Based Compensation

The Company recognizes compensation expense using a fair-value based method related to stock options and other share-based compensation. The expense is measured based on the grant date fair value of the awards that are expected to vest and is recorded over the applicable requisite service period. In the absence of an observable market price for a share-based award, the fair value is based upon a valuation methodology that takes into consideration various factors, including the exercise price of the award, the expected term of the award, the current price of the underlying shares, the expected volatility of the underlying share price based on peer companies, the expected dividends on the underlying shares and the risk-free interest rate.

Property and Equipment

The Company records property and equipment at cost less accumulated depreciation. The Company records depreciation using the straight-line method, based on the following estimated useful lives:

Furniture and equipment	5-10 years
Computer equipment and software	2-5 years

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NOTES TO COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
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Operating Leases

The Company records rent expense for operating leases on a straight-line basis over the term of the lease. The Company begins amortization on the date of initial possession, which is generally when the Company enters the space and begins to make improvements in preparation for its intended use. The Company accounts for the difference between rent expense and rent paid as deferred rent. The Company records a deferred rent liability at the inception of the lease term and amortizes the deferred rent over the term of the lease as a reduction to rent expense.

Goodwill

The Company records as goodwill the excess of the purchase price of a business acquired over the fair value of net tangible assets and identifiable intangible assets at the date of the acquisition. The Company evaluates goodwill for impairment on an annual basis each October 1 or more frequently if events or changes in circumstances indicate that goodwill might be impaired. Any impairment could have a material adverse effect on the Company's financial condition and results of operations.

Short-Term Investments

Short-term investments consist of restricted cash accounts that are subject to contractual withdrawal restrictions and penalties. As described in Note 7, under the Loan Agreement with MidCap Funding III, LLC and Silicon Valley Bank, the Company is required to maintain a cash balance with Silicon Valley Bank in an amount of not less than \$10.0 million until mid-January 2012. The Company's short-term investments represent cash accounts and money market funds that hold short-term U.S. Treasury securities.

Acquired In-Process Research and Development (IPR&D)

Acquired IPR&D represents the fair value assigned to research and development programs that the Company acquires that have not been completed at the date of acquisition and which have no future alternative use. The value assigned to acquired IPR&D is determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting net cash flows from the projects and discounting the net cash flows to present value. Additionally, the Company's estimates take into account the relevant market size and growth factors, expected trends in technology and the nature and expected timing of new product introductions by the Company and its competitors. The resulting net cash flows from such programs are based on management's estimates of cost of sales, operating expenses and income taxes from such programs. The rates utilized to discount the net cash flows to their present value are commensurate with the stage of development of the program and uncertainties in the economic estimates used in the projections described above. Acquired IPR&D assets are amortized, once the related project has been successfully developed and regulatory approval for a product launch obtained, over their estimated useful lives. As of December 31, 2010 and 2011, there was no IPR&D recorded on the Company's consolidated balance sheets.

Realizability of Carrying Value of Long-Lived Assets

The Company reviews the recoverability of long-lived and finite-lived intangible assets when circumstances indicate that the carrying amount of assets might not be recoverable. The Company bases this evaluation on various analyses, including undiscounted cash flow projections. In the event undiscounted cash flow projections indicate impairment, the Company would record an impairment based on the fair value of the assets at the date of the impairment.

FURIEX PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
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(dollars and shares in tables in thousands)

Recent Accounting Pronouncements

In October 2009, the Financial Accounting Standards Board, or FASB, issued a new accounting standard related to the accounting for revenue arrangements with multiple deliverables. This standard applies to all deliverables in contractual arrangements in all industries in which a vendor will perform multiple revenue-generating activities. This standard also addresses the unit of accounting for an arrangement involving multiple deliverables and how arrangement consideration should be allocated. The Company's adoption of this standard on January 1, 2011 did not have a material impact on the Company's combined and consolidated financial statements.

In March 2010, the FASB issued a new accounting standard, the objective of which is to establish a revenue recognition model for contingent consideration that is payable upon the achievement of an uncertain future event, referred to as a milestone. The Company's adoption of this standard on January 1, 2011 did not have a material impact on the Company's combined and consolidated financial statements.

In September 2011, the FASB issued an update to the accounting standard that permits an entity to make a qualitative assessment of whether it is more likely than not that a reporting unit's fair value is less than its carrying value before applying the two-step goodwill impairment model that is currently required. If it is determined through the qualitative assessment that a reporting unit's fair value is, more likely than not, greater than its carrying value, the remaining impairment steps would be unnecessary. The qualitative assessment is optional, allowing companies to proceed directly to the quantitative assessment. This update is effective for annual and interim goodwill impairment tests performed in fiscal years beginning after December 15, 2011; however, early adoption is permitted. The Company did not early adopt this standard and is currently evaluating the impact this update will have on its combined and consolidated financial statements.

2. Spin-off from Pharmaceutical Product Development Inc.

On June 14, 2010, PPD spun off its compound partnering business through the spin-off of Furiex. PPD contributed substantially all of the compound partnering business components of the discovery sciences segment and \$100.0 million of cash to Furiex. All outstanding shares of Furiex were then distributed to PPD shareholders of record on June 1, 2010 as a pro-rata, tax-free dividend of one share of Furiex common stock for every twelve shares of PPD's common stock.

In connection with the spin-off, the Company and PPD entered into a series of agreements, including a separation and distribution agreement, transition services agreement, sublease and license agreements, employee matters agreement, tax sharing agreement and a master development services agreement.

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The total amount of the Furiex contribution of \$152.4 million was based on the book value of the net assets that were transferred to Furiex in connection with the spin-off, as follows:

	<u>2010</u>
Net book value of assets transferred:	
Cash	\$100,000
Accounts receivable	7,705
Prepaid expenses	100
Property and equipment, net	18
Goodwill	49,116
Accounts payable	(758)
Accrued expenses and other current liabilities	(3,542)
Long-term liabilities	<u>(201)</u>
Net assets transferred	<u>\$152,438</u>

3. Acquisitions and Dispositions

Magen Biosciences, Inc.

In April 2009, PPD acquired 100 percent of the outstanding equity interests of Magen BioSciences, Inc., or Magen, a biotechnology company focused on the development of dermatologic therapies, for total consideration of \$14.9 million. Of this amount, PPD paid \$13.1 million at closing and deposited the remaining \$1.8 million into an escrow account to secure indemnification claims. None of the business assets or liabilities of Magen, including the funds in the escrow account, were contributed to the Company in the spin-off, and all rights and liabilities remained with PPD after the spin-off on June 14, 2010.

Acquisition costs related to Magen were \$0.2 million and were included in selling, general and administrative expenses in the combined and consolidated statements of operations.

PPD accounted for this acquisition under the purchase method of accounting. Accordingly, the purchase price for this acquisition was allocated to the estimated fair value of assets acquired and liabilities assumed, which are set forth in the following table:

	<u>Magen</u>
Assets acquired:	
Current assets, including cash of \$939	\$ 2,991
Net property and equipment	609
Goodwill	3,987
Value of identifiable intangible assets:	
In-process research and development	<u>10,361</u>
Total assets acquired	<u>\$17,948</u>
Liabilities assumed:	
Current liabilities	<u>\$ 3,082</u>
Total liabilities assumed	<u>3,082</u>
Net assets acquired	<u>\$14,866</u>

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The goodwill associated with PPD's acquisition of Magen was associated with PPD's anticipated access to additional dermatology compounds. The acquired in-process research and development listed above was related solely to the MAG-131 research program. PPD filed an Investigational New Drug application, or IND, for MAG-131 in October 2009, but subsequently suspended the program for that compound due to unfavorable efficacy data that was discovered in late 2009. As a result, PPD evaluated the asset for impairment and determined the asset was impaired and recorded a charge of \$10.4 million as of December 31, 2009, presented in discontinued operations in the accompanying combined and consolidated statement of operations. As described below, in May 2010, PPD subsequently discontinued the operations of its wholly owned subsidiary PPD Dermatology, Inc., formerly Magen.

Piedmont Research Center, LLC and PPD Biomarker Discovery Sciences, LLC

In May 2009, PPD completed its disposition of substantially all of the assets of its wholly owned subsidiary Piedmont Research Center, LLC for total consideration of \$46.0 million. The purchaser had an indemnification holdback of \$3.5 million. PPD received this additional payment in the first quarter of 2010. Piedmont Research Center, LLC provided pre-clinical research testing services for clients with anti-cancer and other therapeutic candidates.

In December 2009, PPD completed its disposition of PPD Biomarker Discovery Sciences, LLC for total consideration of \$0.1 million and the right to receive a percentage of future revenues. This right remained with PPD as part of the spin-off. PPD Biomarker Discovery Sciences, LLC provided biomarker discovery services.

Discontinued Operations

Due to the unique service offerings of Piedmont Research Center, LLC and PPD Biomarker Discovery Sciences, LLC, PPD determined these business units were no longer a long-term strategic fit and elected to sell them. As a result, these business units are shown as discontinued operations for 2009.

Due to unfavorable efficacy data associated with the MAG-131 program, PPD discontinued the operations of its wholly owned subsidiary PPD Dermatology, Inc. As a result, this business unit is shown as discontinued operations for 2009 and 2010.

The results of these business units are reported as discontinued operations within the combined and consolidated statements of operations as set forth in the following table:

	<u>2009</u>	<u>2010</u>
Revenue	\$ 7,058	\$ —
Gain on sale of business	26,707	—
Loss from discontinued operations	<u>(27,339)</u>	<u>(5,133)</u>
Loss from discontinued operations, net of income taxes	<u>\$ (632)</u>	<u>\$(5,133)</u>

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(dollars and shares in tables in thousands)

4. Property and Equipment

Property and equipment, stated at cost, consisted of the following amounts on the dates set forth below:

	<u>December 31,</u>	
	<u>2010</u>	<u>2011</u>
Furniture and equipment	\$ 30	\$ 97
Computer equipment and software	214	223
Total property and equipment	244	320
Less accumulated depreciation	(56)	(139)
Total property and equipment, net	<u>\$188</u>	<u>\$ 181</u>

Noncash investing activity related to liabilities that remain unpaid for the acquisition of property and equipment as of December 31, 2011 was approximately \$0.05 million.

5. Goodwill and Intangible Assets

The Company reviews goodwill for impairment annually on October 1 and whenever events or changes in circumstances indicate that the carrying amount of an asset might not be recoverable. This analysis utilizes a discounted cash flow method using the expected future inflows and outflows of the business and an appropriate discount rate. Based on the review as of October 1, 2011, the Company's calculated fair value of equity was in excess of carrying value.

The fair value of goodwill could be materially impacted by future adverse changes such as future declines in operating results, a decline in the valuation of pharmaceutical and biotechnology company stocks, including the valuation of the Company's own common stock, a slowdown in the worldwide economy or the pharmaceutical and biotechnology industry, failure to meet the performance projections included in forecasted operating results or the delay or abandonment of any research and development programs.

During 2009, PPD acquired in-process research and development of \$10.4 million through the acquisition of Magen, which was related solely to the MAG-131 research program. At the time of acquisition, this program was in the pre-IND application phase of research. PPD estimated that it would take approximately four to five years to complete research and development. The fair value of the in-process research and development was determined using the discounted cash flow method. The discounted cash flow was determined based upon projected revenue, expenses and contributory assets related to the specific project and a discount rate based upon the overall weighted average cost of capital for the asset and the additional risk related to the uncertainty of the project. PPD also assessed the current status of development, nature and timing of efforts to complete such development, uncertainties and other factors when estimating the fair value.

PPD filed an IND for MAG-131 in October 2009, but subsequently suspended the program for that compound due to unfavorable efficacy data that was discovered in late 2009. As a result, PPD evaluated the asset for impairment. PPD reassessed the fair value of the program using a discounted cash flow model based on Level 3 inputs such as the estimated remaining costs to develop the acquired technology into commercially viable products, estimated net cash flows from the program and a discount rate commensurate with the stage of development of the program. Based on this analysis, PPD determined that the acquired in-process research and

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development asset was impaired and recorded a charge of \$10.4 million as of December 31, 2009, presented in discontinued operations in the accompanying combined and consolidated statements of operations. Because the intangible asset was an indefinite-lived asset, PPD had not amortized this asset during 2009.

6. Accrued Expenses

Accrued expenses consisted of the following amounts on the dates set forth below:

	<u>December 31,</u>	
	<u>2010</u>	<u>2011</u>
Salaries, wages, benefits and related costs	\$ 1,225	\$ 1,346
Research and development costs	12,225	8,681
Professional fees	131	200
Interest	—	88
Other	186	107
	<u>\$13,767</u>	<u>\$10,422</u>

7. Long-Term Debt

On August 18, 2011, the Company and its subsidiaries entered into a Loan and Security Agreement with MidCap Funding III, LLC and Silicon Valley Bank, collectively, the Lenders. Each Lender had an initial term loan commitment of up to \$7.5 million under the Loan Agreement, giving the Company a potential available amount of \$15.0 million. As of December 31, 2011, the remaining amount potentially available to the Company is \$5.0 million.

The loans are divided into two separate tranches. The first tranche of \$10.0 million closed on August 18, 2011. The second tranche of \$5.0 million only becomes available to the Company if a pre-defined financing event occurs prior to March 31, 2012. The first tranche bears interest at a fixed rate of 10.25% per annum and is due August 1, 2015. Interest accrues monthly and is payable on the first day of the following month, in arrears. Principal payments of the first tranche begin on August 1, 2012, are due the first day of each month, and will be paid on a ratable monthly basis until maturity. The Company intends to use the proceeds from the loans to support research and development for its clinical stage compounds JNJ-Q2 and MuDelta.

A final payment fee is due to the Lenders in an amount equal to 2.5% of the loan commitments, payable at the maturity date or earlier prepayment of the loans. The Company may prepay the first tranche subject to a prepayment fee of between one and four percent of the amount borrowed, depending on the time of the prepayment. The amount of interest expense related to the Loan Agreement included in the statements of operations for the year ended December 31, 2011 was \$0.4 million. Included in this amount is the ratable accrual over the term of the loan of the final payment fee, payable upon the maturity date, which is presented in other long-term liabilities within the consolidated balance sheets.

Under the Loan Agreement, the Company and its subsidiaries are subject to affirmative covenants, including the obligations to maintain good standing, provide certain notices to the Lenders, deliver financial statements to the Lenders, maintain insurance, discharge all taxes, protect intellectual property and protect collateral. The Company and its subsidiaries are also subject to negative covenants, including that it may not enter into a merger or consolidation or certain change of control events, incur liens on the collateral, incur additional indebtedness,

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dispose of any property, change its jurisdictions of organization or organizational structures or types, declare or pay dividends (other than dividends payable solely in common stock), make certain investments or acquisitions, and enter into certain transactions with affiliates, in each case subject to certain customary exceptions, including exceptions that allow the Company and its subsidiaries to acquire additional compounds and to enter into licenses and similar agreements providing for the use and collaboration of the Company's and its subsidiaries' intellectual property provided certain conditions are met. In addition, under the Loan Agreement the Company is required to maintain a cash balance with Silicon Valley Bank in an amount of not less than \$10.0 million until mid-January 2012. The Company's cash, cash equivalents and short-term investment accounts serve as collateral for the loan. The Company is currently in compliance with its obligations under the Agreement.

The Loan Agreement provides that events of default include failure to make payment of principal or interest on the loan when required, failure to perform certain obligations under the Loan Agreement and related documents, defaults in certain other indebtedness and certain other events including certain adverse actions taken by the Food and Drug Administration or other governmental authorities. Upon events of default, the Company's obligations under the Loan Agreement may, or in the event of insolvency or bankruptcy will automatically, be accelerated. Upon the occurrence of any event of default, the Company's obligations under the Loan Agreement will bear interest at a rate equal to the lesser of (a) 4% above the rate of interest applicable to such obligations immediately prior to the occurrence of the event of default and (b) the maximum rate allowable under law.

As of December 31, 2011, maturities of debt per the Loan Agreement for each of the next five years were as follows:

2012	\$ 1,351
2013	3,243
2014	3,243
2015	2,163
2016	—
	<u>\$10,000</u>

8. Lease Obligations

The Company is currently obligated under operating leases or subleases for six locations relating to office space and associated building expenses. These leases with PPD and other third parties expire at various dates in 2012 and 2013, with renewal terms for two locations for up to one year. Prior to the spin-off, the Company recognized operating lease expense for leases which were acquired as part of the Magen acquisition. However, these operating leases obligations remained with PPD as of the spin-off date.

Rental expense related to operating leases has been recorded in continuing operations in the amounts of \$0.09 million and \$0.2 million for the year ended December 31, 2010 and 2011, respectively. Amounts recorded in discontinued operations were \$0.3 million for the year ended December 31, 2009.

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As of December 31, 2011, future minimum payments for lease obligations for subsequent years were as follows:

2012	\$115
2013	38
	<u>\$153</u>

9. Share-Based Compensation

Equity Compensation Plan—Furiex Plan

The Company has adopted an equity incentive plan, the Furiex Pharmaceuticals, Inc. 2010 Stock Plan (the “Plan”). The Company is authorized to issue a total of 1,778,641 shares under the Plan. The Plan is intended to provide incentives to employees, directors and consultants through the issuance of common stock-based awards, including restricted stock, stock options, stock appreciation rights and other equity based awards. The plan is administered by a committee designated by its board of directors.

During the years ended December 31, 2010 and 2011, the Company granted 839,642 and 742,234 stock options to employees, directors, and consultants, with a weighted-average exercise price of \$9.11 and \$13.87, respectively. All options were granted with an exercise price equal to the fair value of the Company’s common stock on the grant date. The fair value of the Company’s common stock on the grant date is equal to the most recent Nasdaq closing price of the Company’s stock on the date of grant.

The Company recognizes compensation expense using a fair-value based method related to stock options and other share-based compensation. The expense is measured based on the grant date fair value of the awards that are expected to vest and is recorded over the applicable requisite service period on a straight-line basis. The options granted vest per one of the following schedules: (1) after a period of one year (or less in the case of certain 2011 Director grants); (2) ratably over three years on the anniversary date of grant; or (3) one-third vest on grant date and the remaining ratably over two years on the anniversary date of grant. The options expire on the earlier of ten years from the date of grant, or within specified time limits following termination of employment, retirement or death. Shares are issued from authorized, but unissued stock. The Company does not pay dividends on unexercised options.

The weighted-average grant date fair value per share was determined using the Black-Scholes option-pricing method. The weighted-average grant date fair value per share and aggregate fair value of options granted to employees and directors during the year ended December 31, 2010 was \$5.95 and \$3.8 million, respectively. The weighted-average grant date fair value per share and aggregate fair value of options granted to employees and directors during the year ended December 31, 2011 was \$8.51 and \$5.5 million, respectively. The weighted-average grant date fair value per share and aggregate fair value of options granted to consultants during the year ended December 31, 2010, was \$7.36 and \$1.5 million, respectively. The weighted-average grant date fair value per share and aggregate fair value of options granted to consultants during the year ended December 31, 2011, was \$9.71 and \$1.0 million, respectively.

The amount of stock compensation expense related to consultant option grants, classified in selling, general and administrative expenses within the combined and consolidated statements of operations, is marked to market at the end of each financial reporting period until such options vest using the Black-Scholes option-pricing

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method and the period end closing stock price. These non-employee grants relate to a consulting agreement executed with the Company's founding Chairman, Dr. Fred Eshelman. The terms of this consulting agreement provide for a grant of stock options to purchase shares of the Company's common stock equal to 2.0% of the Company's common stock outstanding immediately after the completion of the spin-off, and additional stock options for an additional 1.0% on or about the second anniversary of the spin-off date. All options related to this consulting agreement had been granted as of December 31, 2011.

For the years ended December 31, 2010 and 2011, stock-based compensation cost for the Company's employees, directors and consultants under the Plan totaled \$1.2 million and \$4.2 million, respectively, and is included in the accompanying combined and consolidated financial statements. For the year ended December 31, 2011, the Company received \$0.6 million of cash from the exercise of stock options granted by the Company. For the year ended December 31, 2010, no cash was received by the Company from the exercise of stock options granted by the Company as no options vested during the year.

A summary of option activity for the Plan as of December 31, 2010 and 2011, and changes during the years, is presented below:

	<u>Shares</u>	<u>Weighted-Average Exercise Price</u>	<u>Weighted-Average Remaining Contractual Life</u>	<u>Aggregate Intrinsic Value</u>
Outstanding at January 1, 2010	—	\$ —		
Granted	840	9.11		
Forfeited	(1)	9.11		
Outstanding at December 31, 2010	<u>839</u>	<u>\$ 9.11</u>		
Exercisable at December 31, 2010	<u>—</u>	<u>—</u>		
Outstanding at January 1, 2011	839	\$ 9.11		
Granted	742	13.87		
Exercised	(68)	9.11		
Forfeited	(1)	9.11		
Outstanding at December 31, 2011	<u>1,512</u>	<u>\$11.45</u>	<u>9.0 years</u>	<u>\$7,951</u>
Exercisable at December 31, 2011	<u>343</u>	<u>\$10.58</u>	<u>8.7 years</u>	<u>\$2,106</u>
Vested or expected to vest at December 31, 2011	<u>1,446</u>	<u>\$11.43</u>	<u>9.0 years</u>	<u>\$7,637</u>

The following table summarizes information about stock options outstanding for the Company as of December 31, 2011:

<u>Range of Exercise Prices</u>	<u>Options Outstanding</u>			<u>Options Exercisable</u>	
	<u>Number Outstanding at 12/31/11</u>	<u>Weighted-Average Remaining Contractual Life</u>	<u>Weighted Average Exercise Price</u>	<u>Number Exercisable at 12/31/11</u>	<u>Weighted- Average Exercise Price</u>
\$9.11—13.00	769	8.5 years	\$ 9.11	257	\$ 9.11
\$13.01—15.00	741	9.6 years	\$13.87	86	\$15.00
\$15.01—16.71	2	10.0 years	\$16.71	—	\$ —
	<u>1,512</u>	<u>9.0 years</u>	<u>\$11.45</u>	<u>343</u>	<u>\$10.58</u>

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The aggregate fair value of the Plan's options granted to the Company's employees, directors and consultants during the years ended December 31, 2010 and 2011 was \$5.3 million and \$6.4 million, respectively. The total intrinsic value (the amount by which the market value of the Company's common stock exceeded the exercise price of the options on the date of exercise) of options exercised during the year ended December 31, 2010 was zero as no options vested, and none were exercised during the year. The total intrinsic value of options exercised during the year ended December 31, 2011 was \$0.5 million.

A summary of the status of unvested options held by the Company's employees, directors and consultants as of December 31, 2011, and changes during the year then ended, is presented below:

<u>Unvested Options</u>	<u>Shares</u>	<u>Weighted-Average Grant Date Fair Value</u>
Unvested at January 1, 2011	839	\$6.29
Granted	742	8.67
Vested	(412)	6.81
Forfeited	(1)	5.97
Unvested at December 31, 2011	<u>1,168</u>	<u>\$7.62</u>

The total fair value of shares vested during the year ended December 31, 2011 was \$3.3 million. As of December 31, 2011, unrecognized compensation expense related to the unvested portion of the Company's stock options granted to employees, directors and consultants was approximately \$7.4 million, and will be recognized over a weighted-average period of 1.9 years for employees and directors and 2.1 years for consultants. There was no associated income tax benefit recognized for the years ended December 31, 2010 and 2011 based on the Company's valuation allowance that is recorded against its net deferred tax assets.

The following tables indicate the assumptions used in estimating fair value of each Plan option granted to employees and directors for the years ended December 31, 2011 and 2010.

	<u>2011</u>
Expected term (years)	5.50-6.00
Dividend yield (%)	—
Risk-free interest rate (%)	1.10-2.18
Expected volatility (%)	65.09-69.97
	<u>2010</u>
Expected term (years)	5.50-6.00
Dividend yield (%)	—
Risk-free interest rate (%)	2.19-2.40
Expected volatility (%)	70.99-71.94

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The following tables indicate the assumptions used in estimating fair value of each Plan option granted to consultants for the years ended December 31, 2011 and 2010.

	<u>2011</u>
Expected term (years)	10.00
Dividend yield (%)	—
Risk-free interest rate (%)	1.92
Expected volatility (%)	67.05
	<u>2010</u>
Expected term (years)	10.00
Dividend yield (%)	—
Risk-free interest rate (%)	3.27
Expected volatility (%)	73.81

Expected option lives were based on the simplified method and volatilities used in fair valuation calculations are based on a benchmark of peer companies with similar expected lives. The Company does not currently intend to pay dividends on common stock; as a result, no dividend yield has been utilized in the fair valuation calculation. The risk-free interest rate is based on the rate at the date of grant for actively traded non-inflation-indexed issues adjusted to constant maturities with a term that approximates the expected term of the option.

Equity Compensation Plan—PPD Plan

For the periods prior to June 14, 2010, some Company employees participated in PPD's equity compensation plan (the "PPD Plan"). The PPD Plan provided for the grant of incentive stock options, non-qualified stock options, restricted stock and other types of equity awards to its directors, officers, employees and consultants. The plan was administered by a committee designated by PPD's board of directors. Some employees of the Company historically received awards from PPD. Accordingly, the following information regarding share-based compensation has been derived from the equity awards granted to Company employees by PPD prior to June 14, 2010. All unvested options granted under the PPD Plan to Company employees were forfeited as of the spin-off date.

The exercise price of each option granted under the PPD Plan was equal to the market price of PPD's common stock on the date of grant, and the maximum exercise term of each option granted did not exceed ten years. Options were granted upon approval of the compensation committee of the board of directors of PPD. The majority of the options vested ratably over a period of three years. The options expire on the earlier of ten years from the date of grant, or within specified time limits following termination of employment, retirement or death. Shares were issued from authorized, but unissued stock. PPD did not pay dividends on unexercised options.

For the years ended December 31, 2009 and 2010, stock-based compensation cost for the Company's employees under the PPD Plan totaled \$0.3 million and \$0.1 million, respectively, and is included in the accompanying combined and consolidated financial statements.

For the years ended December 31, 2009 and 2010, the amount of cash received by PPD from the exercise of PPD stock options granted to the Company's employees was \$1.1 million and \$0.0 million, respectively.

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A summary of option activity under PPD's plan for the Company's employees as of December 31, 2009 and 2010, and changes during the years, is presented below:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at January 1, 2009	235	\$30.33		
Granted	95	27.01		
Exercised	(5)	16.46		
Forfeited	(60)	32.01		
Expired	(28)	28.82		
Outstanding at December 31, 2009	<u>237</u>	<u>\$29.02</u>		
Exercisable at December 31, 2009	<u>154</u>	<u>\$27.96</u>		
Outstanding at January 1, 2010	237	\$29.02		
Forfeited	(100)	28.88		
Expired	(1)	37.42		
Outstanding at December 31, 2010	<u>136</u>	<u>\$27.38</u>		
Exercisable at December 31, 2010	<u>136</u>	<u>\$27.38</u>	4.8 years	\$(191)
Vested at December 31, 2010	<u>136</u>	<u>\$27.38</u>	4.8 years	\$(191)

The following table summarizes information about PPD's stock options outstanding for the Company's employees as of December 31, 2010:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding at 12/31/10	Weighted-Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable at 12/31/10	Weighted- Average Exercise Price
\$19.94—21.00	71	5.9 years	\$20.45	71	\$20.45
\$21.01—34.00	46	3.8 years	\$31.29	46	\$31.29
\$34.01—43.26	19	6.7 years	\$42.26	19	\$42.26
	<u>136</u>	<u>4.8 years</u>	<u>\$27.38</u>	<u>136</u>	<u>\$27.38</u>

All PPD Plan options granted during the year ended December 31, 2009 were granted with an exercise price equal to the fair value of PPD's common stock on the grant date. The fair value of PPD's common stock on the grant date was equal to the Nasdaq closing price of the stock on the date of grant. The weighted-average grant date fair value per share of PPD Plan options granted to the Company's employees during the year ended December 31, 2009 was \$7.55. The aggregate fair value of PPD Plan options granted to the Company's employees during the year ended December 31, 2009 was \$0.7 million. The total intrinsic value (the amount by which the market value of PPD's common stock exceeded the exercise price of the options on the date of exercise) of options exercised during the year ended December 31, 2009 was approximately \$0.02 million.

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A summary of the status of unvested PPD options held by the Company's employees as of December 31, 2010, and changes during the year then ended, is presented below:

<u>Unvested Options</u>	<u>Shares</u>	<u>Weighted-Average Grant Date Fair Value</u>
Unvested at January 1, 2010	83	\$7.80
Vested	(25)	8.88
Forfeited	(58)	7.34
Unvested at December 31, 2010	<u>—</u>	<u>\$ —</u>

As of December 31, 2010, there was no unrecognized compensation cost related to unvested PPD stock options held by the Company's employees as all unvested PPD Plan options which were not vested as of the spin-off date were forfeited. The total fair value of shares vested during the years ended December 31, 2009 and 2010 was \$0.6 million and \$0.2 million, respectively.

The fair value of each PPD Plan option grant was estimated on the grant date using the Black-Scholes option-pricing model. The following table indicates the assumptions used in estimating fair value for the year ended December 31, 2009.

	<u>2009</u>
Expected term (years)	3.50
Dividend yield (%)	1.72-2.74
Risk-free interest rate (%)	1.14-1.67
Expected volatility (%)	36.58-39.27

The expected term represents an estimate of the period of time options are expected to remain outstanding and is based on historical exercise and termination data. The dividend yield was based on the most recent dividend payment over the market price of the PPD stock at the beginning of the period. The risk-free interest rate was based on the rate at the date of grant for a zero-coupon U.S. Treasury bond with a term that approximates the expected term of the option. Expected volatilities were based on the historical volatility of PPD's stock price over the expected term of the options.

Employee Stock Purchase Plan—PPD Plan

For the periods prior to December 31, 2009, some of the Company's employees participated in PPD's employee stock purchase plan (the "PPD ESPP"). No Company employees participated in PPD's employee stock purchase plan during the year ended December 31, 2010.

The PPD ESPP had two six-month offering periods (each an "Offering Period") each year, beginning January 1 and July 1, respectively. Eligible employees could elect to make payroll deductions from 1% to 15% of their base pay during each payroll period of an Offering Period. None of the contributions made by eligible employees to purchase PPD's common stock under the PPD ESPP were tax-deductible to the employees. The purchase price was 90% of the lesser of (a) the reported closing price of PPD's common stock for the first day of the Offering Period or (b) the reported closing price of the common stock for the last day of the Offering Period.

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Employees eligible to participate in the PPD ESPP included employees of the Company, except employees who customarily worked less than 20 hours per week or five months in a year.

The fair value of each PPD ESPP share was estimated using the Black-Scholes option-pricing model. The following table indicates the assumptions used in estimating fair value for the year ended December 31, 2009.

	<u>2009</u>
Expected term (years)	0.50
Dividend yield (%)	1.72-2.58
Risk-free interest rate (%)	0.27-0.35
Expected volatility (%)	31.32-36.68

The Company's compensation costs for the PPD ESPP, as determined based on the fair value of the discount and option feature of the underlying PPD ESPP grant, were approximately \$0.1 million for year ended December 31, 2009. The weighted-average grant date fair value per share during the year ended December 31, 2009 was \$4.16.

For the year ended December 31, 2009, the value of stock issued to Company employees for PPD ESPP purchases was \$0.3 million.

During the year ended December 31, 2009, the Company's employees contributed \$0.3 million to the PPD ESPP for the purchase of approximately 13,300 shares. The aggregate fair value of shares purchased during the year ended December 31, 2009 was \$0.4 million. Contributions for the second Offering Period of 2009 were not used to purchase shares until January 2010.

10. Income Taxes

Taxes computed at the statutory U.S. federal income tax rate of 35% are reconciled to the provision for income taxes as follows:

	<u>Year Ended December 31,</u>		
	<u>2009</u>	<u>2010</u>	<u>2011</u>
Effective tax rate	<u>0%</u>	<u>0%</u>	<u>0%</u>
Statutory rate of 35%	\$(2,905)	\$(17,329)	\$(17,138)
State taxes, net of federal benefit	—	(2,031)	(284)
Permanent differences	(22)	111	371
Change in valuation allowance	3,776	10,119	17,065
Net operating loss and related items offset by former Parent Company consolidated group	(849)	9,144	—
Provision for income taxes	<u>\$ —</u>	<u>\$ 14</u>	<u>\$ 14</u>

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Components of the current deferred tax assets (liabilities) were as follows:

	<u>December 31,</u>	
	<u>2010</u>	<u>2011</u>
Accrued expenses	\$ 254	\$ 435
Valuation allowance	(254)	(435)
Total current deferred tax asset (liability)	<u>\$ —</u>	<u>\$ —</u>

Components of the long-term deferred tax assets (liabilities) were as follows:

	<u>December 31,</u>	
	<u>2010</u>	<u>2011</u>
Other depreciation and amortization	\$ 2,938	\$ 2,399
Stock options	349	1,290
Future benefit of carryforward losses	13,385	29,853
Valuation allowance	(16,864)	(33,748)
Total long-term deferred tax asset (liability)	<u>\$ (192)</u>	<u>\$ (206)</u>

For the year ended December 31, 2010 and 2011, the Company has recorded an insignificant amount of income tax expense. This amount relates to the adjustment of a deferred tax liability associated with historical goodwill, which is deductible for tax purposes, but is an indefinite lived intangible asset for financial reporting. The amounts reflected in the statements of operations for the year ended December 31, 2010 and 2011 are the tax effect of the tax amortization of this item. Because the associated deferred tax liability relates to an indefinite lived intangible, the Company does not consider this item in computing the valuation allowance related to the Company's net deferred tax assets. As of December 31, 2010 and 2011, the deferred tax liability associated with this intangible asset, reflected in other long-term liabilities within the combined and consolidated balance sheets, was approximately \$0.2 million.

The Company has determined that any uncertain tax positions for the tax years open for examination would have no material impact on the combined and consolidated financial statements of the Company.

The Company has federal operating loss carry forwards of approximately \$79.3 million that will expire in 2030. The Company also has state operating loss carry forwards of approximately \$46.5 million that will begin to expire in 2013.

11. Employee Savings Plan

Savings plan

For the periods prior to June 14, 2010, Company employees participated in PPD's 401(k) Retirement Savings Plan. PPD's plan matched 50% of an employee's savings up to 6% of pay and those contributions vested ratably over a four-year period. PPD's contributions to the plan, net of forfeitures, were \$0.1 million and \$0.09 million for the years ended December 31, 2009 and 2010, respectively.

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For the periods after June 14, 2010, Company employees participate in the Furiex 401(k) Retirement Savings Plan. The Company's plan matches 100% of an employee's savings up to 4% of the employee's deferral, and those contributions vest immediately. The Company's contributions to the plan, net of forfeitures, were \$0.06 million and \$0.14 million for the years ended December 31, 2010 and 2011, respectively.

12. Commitments and Contingencies

The Company is involved in compound development and commercialization collaborations. The Company developed a risk-sharing research and development model with pharmaceutical and biotechnology companies to advance compounds to commercialization. Through collaborative arrangements based on this model, the Company works with its collaborators by sharing the risks and potential rewards associated with the development and commercialization of drugs with its collaborators. As of December 31, 2011, the Company's four main collaborations were with Janssen Pharmaceutica, N.V., or Janssen (an affiliate of Johnson & Johnson), Ranbaxy Laboratories, Ltd., or Ranbaxy, Alza Corporation, or Alza, and Takeda Pharmaceuticals Company Limited, and relate to, respectively: the JNJ-Q2 and MuDelta compounds; a statin compound, or PPD-10558; the product Priligy; and the product Nesina.

As of December 31, 2011, the Company had three collaborations that involve potential future expenditures. The first is its collaboration with Alza for Priligy. In connection with this collaboration, the Company has an obligation to pay a royalty to Eli Lilly and Company of 5% on annual net sales of the compound in excess of \$800.0 million. As of December 31, 2011, the Company is not obligated to pay any ongoing costs of development for this compound.

The second collaboration involving future expenditures is in respect of the two compounds in-licensed from Janssen: JNJ-Q2 and MuDelta. On April 18, 2011, Janssen announced that in connection with a broad strategic review of its portfolio of infectious disease programs, it will be redirecting its research and development efforts toward antivirals and vaccines, and will not be investing in the development of new antibacterial therapies. As a result, Janssen elected not to exercise its option to continue the development of the JNJ-Q2 compound. On April 19, 2011, the Company announced it had acquired full exclusive license rights to develop and commercialize the JNJ-Q2 compound under its existing development and license agreement with Janssen. On November 1, 2011, the Company announced it had acquired full exclusive license rights to develop and commercialize the MuDelta compound under its existing development and license agreement with Janssen. The Company acquired these rights as a result of Janssen's decision not to exercise its option under the agreement to continue development of MuDelta.

The Company plans to continue evaluating other partnering and funding opportunities for both the JNJ-Q2 and MuDelta compounds. The Company may be obligated to pay Janssen, for both the JNJ-Q2 and MuDelta compounds, individually, up to \$50.0 million in regulatory milestone payments and, if approved for marketing, up to \$75.0 million in sales-based milestone payments and sales-based royalties increasing from the mid- to upper-single digit percentages as sales volume increases. Royalties would be paid for a period of ten years after the first commercial sale or, if later, the expiration of the last valid patent claim or the expiration of patent exclusivity.

The third collaboration involving future expenditures is with Ranbaxy for a statin compound, PPD-10558. In December 2006, the Company entered into an exclusive license agreement with Ranbaxy for rights to PPD-10558. In December 2011, the Company announced preliminary results from the Phase II trial of

FURIEX PHARMACEUTICALS, INC. AND SUBSIDIARIES
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(dollars and shares in tables in thousands)

PPD-10558. Based on these results, the Company has discontinued further spending on the PPD-10558 program and plans to terminate the license agreement with Ranbaxy in accordance with the terms of the agreement. The Company will owe Ranbaxy a \$1.0 million development milestone payment upon completion of the Phase II final study report, which the Company believes will occur in the second quarter of 2012.

The Company currently maintains insurance for risks associated with the operation of its business. These policies provide coverage for a variety of potential losses, including loss or damage to property, bodily injury, general commercial liability and product liability.

The Company might be a party to various claims and legal proceedings in the normal course of business. As of December 31, 2011, there are no outstanding claims that management believes will have a material effect upon the Company's financial condition, results of operations or cash flows.

13. Fair Value of Financial Instruments

Cash and Cash Equivalents, Short-Term Investments, Accounts Receivable, Accounts Payable and Accrued Expenses

The carrying amount of cash and cash equivalents, short-term investments, accounts receivable, accounts payable and accrued expenses approximates fair value because of the short maturity of these items. The Company considers all cash on deposit and money market accounts with original maturities of three months or less at time of purchase to be cash and cash equivalents. Short-term investments consist of restricted cash accounts that are subject to contractual withdrawal restrictions and penalties. The Company's cash and cash equivalents and short-term investments represent cash accounts and money market funds which invest in short-term U.S. Treasury securities with insignificant rates of return.

Long-Term Debt

The fair value of long-term debt approximates its carrying value due to the lack of any changes in the underlying interest rate or the Company's creditworthiness subsequent to the issuance of such debt on August 18, 2011.

14. Related Party Transactions

Pharmaceutical Product Development, Inc. Net Investment

The following table reflects a summary of the transfers to/from parent included in the combined and consolidated statements of shareholders' equity related to changes in Pharmaceutical Product Development, Inc. net investment for the periods prior to the spin-off date:

	<u>2009</u>	<u>2010</u>
Corporate overhead allocations	\$ 712	\$ 1,007
Research and development services	4,416	8,376
Cash from parent for acquisitions	21,503	—
Transfer of proceeds from sale of businesses	(40,267)	(3,464)
Transfers to (from) parent, net	16,313	10,127
Total	<u>\$ 2,677</u>	<u>\$16,046</u>

FURIEX PHARMACEUTICALS, INC. AND SUBSIDIARIES
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(dollars and shares in tables in thousands)

Corporate Overhead Allocations

For the periods prior to the June 14, 2010 spin-off, the Company's operations were fully integrated with PPD, including executive services, finance, treasury, corporate income tax, human resources, information technology, facilities, legal services and investor relations services. The accompanying combined and consolidated financial statements reflect the application of estimates and allocations of operating expenses. Management believes the methods used to allocate these operating expenses were reasonable. The allocation methods included relative time devoted by executive management to the Company's business, and the related benefit received by the Company for other services.

Allocations of expense for these services of \$0.1 million and \$0.6 million associated with continuing operations and \$0.6 million and \$0.5 million associated with discontinued operations for the years ended December 31, 2009 and 2010, respectively, are reflected in the accompanying combined and consolidated statements of operations.

Research and Development Services

PPD performed drug development work for the Company as a related party prior to June 14, 2010 and the expenses related to these services are included in research and development expenses in the accompanying combined and consolidated set of financial statements. Such amounts were \$4.4 million and \$8.4 million for the years ended December 31, 2009 and 2010, respectively.

The Company was provided services by PPD after the spin-off on June 14, 2010. Two members of the Company's Board of Directors previously held board positions with PPD. Expenses paid to PPD for the year ended December 31, 2010 and 2011 by the Company were approximately \$24.5 million and \$30.6 million, respectively.

Cash Transferred from Parent for Acquisitions

During 2009, PPD acquired Magen Biosciences, Inc. (see Note 3) and entered into the Janssen collaboration (see Note 12). These transactions were funded by PPD through transfers of \$21.5 million in cash and assets to the Company.

Transfer of Proceeds from Sale of Business

As discussed in Note 3, PPD disposed of Piedmont Research Center, LLC and PPD Biomarker Discovery Sciences, LLC during 2009. The cash proceeds of \$40.3 million received from these transactions in 2009 were transferred to PPD. The cash proceeds of \$3.5 million received from these transactions in 2010 for the payment of an outstanding escrow account were transferred to PPD.

15. Segment Information

The Company's business consists solely of compound development and partnering activities. Accordingly, the Company operates in one reportable business segment.

FURIEX PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2009, 2010 AND 2011
(dollars and shares in tables in thousands)

16. Quarterly Financial Data (unaudited)

	<u>First</u>	<u>Second</u>	<u>Third</u>	<u>Fourth</u>	<u>Total</u>
<u>2010</u>					
Total revenue ^(a)	\$ 293	\$ 8,113	\$ 288	\$ 289	\$ 8,983
Operating loss	(8,595)	(8,101)	(21,175)	(11,650)	(49,521)
Loss from continuing operations	(8,590)	(8,103)	(21,180)	(11,653)	(49,526)
Loss from discontinued operations, net of income taxes	(2,090)	(3,043)	—	—	(5,133)
Net loss	(10,680)	(11,146)	(21,180)	(11,653)	(54,659)
Loss from continuing operations per basic and diluted share	\$ (0.87)	\$ (0.82)	\$ (2.14)	\$ (1.18)	\$ (5.01)
Loss from discontinued operations, net of income taxes per basic and diluted share	\$ (0.21)	\$ (0.31)	\$ —	\$ —	\$ (0.52)
Net loss per basic and diluted share	\$ (1.08)	\$ (1.13)	\$ (2.14)	\$ (1.18)	\$ (5.53)
<u>2011</u>					
Total revenue	\$ 361	\$ 872	\$ 1,272	\$ 1,985	\$ 4,490
Operating loss	(14,359)	(14,876)	(12,871)	(6,450)	(48,556)
Net loss	(14,365)	(14,882)	(13,013)	(6,721)	(48,981)
Net loss per basic and diluted share	\$ (1.45)	\$ (1.51)	\$ (1.32)	\$ (0.68)	\$ (4.96)

(a) The second quarter of 2010 includes \$7.5 million in milestone revenue resulting from a milestone payment earned upon regulatory and pricing approvals of Nesina in Japan.

Subsidiaries of Furiex Pharmaceuticals, Inc.

<u>Subsidiary</u>	<u>Jurisdiction</u>
APBI Holdings, LLC	North Carolina
Development Partners, LLC	Delaware
Genupro, Inc.	North Carolina

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in Registration Statement No. 333-167552 on Form S-8 of our reports dated March 7, 2012, relating to the combined and consolidated financial statements of Furiex Pharmaceuticals, Inc. and subsidiaries (the "Company"), and the effectiveness of the Company's internal control over financial reporting, appearing in this Annual Report on Form 10-K of the Company for the year ended December 31, 2011.

/s/ DELOITTE & TOUCHE LLP
Raleigh, North Carolina
March 7, 2012

**CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, June S. Almenoff, certify that:

1. I have reviewed this annual report on Form 10-K of Furiex Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any changes in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting that are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal controls over financial reporting.

March 7, 2012

/s/ June S. Almenoff

June S. Almenoff
President and Chief Medical Officer
(principal executive officer)

**CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Marshall H. Woodworth, certify that:

1. I have reviewed this annual report on Form 10-K of Furiex Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any changes in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting that are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal controls over financial reporting.

March 7, 2012

/s/ Marshall H. Woodworth

Marshall H. Woodworth
Chief Financial Officer, Treasurer and Assistant Secretary
(principal financial and accounting officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Furiex Pharmaceuticals, Inc. (the "Company") on Form 10-K for the period ended December 31, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, June S. Almenoff, President and Chief Medical Officer (principal executive officer), of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the Report.

/s/ June S. Almenoff

June S. Almenoff
President and Chief Medical Officer
(principal executive officer)

March 7, 2012

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Furiex Pharmaceuticals, Inc. (the "Company") on Form 10-K for the period ended December 31, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Marshall H. Woodworth, Chief Financial Officer, Treasurer and Assistant Secretary (principal financial and accounting officer) of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the Report.

/s/ Marshall H. Woodworth

Marshall H. Woodworth
Chief Financial Officer, Treasurer and Assistant Secretary
(principal financial and accounting officer)

March 7, 2012

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Wyrick Robbins Yates & Ponton LLP
ATTORNEYS AT LAW

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PO Drawer 17803, Raleigh, NC 27619

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SEC
Mail Processing
Section

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Washington DC
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April 11, 2012

VIA FEDERAL EXPRESS

Securities and Exchange Commission
450 Fifth Street N.W.
Washington, D.C. 20549
Attention: Filing Desk, Mail Stop 1-4

Re: Furiex Pharmaceuticals, Inc.

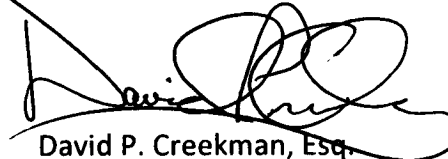
Ladies and Gentlemen:

Pursuant to Rule 14a-3(c) promulgated under the Securities Exchange Act of 1934, enclosed for the Staff's information please find seven copies of the 2011 Annual Report of Furiex Pharmaceuticals, Inc. Please be advised that the enclosed document is being submitted for the information of the Staff only, and shall not be deemed to be "filed" pursuant to the Securities Exchange Act of 1934.

Please date-stamp the enclosed copy of this letter to acknowledge receipt hereof and return it to me in the enclosed stamped envelope. Thank you.

Sincerely,

WYRICK ROBBINS YATES & PONTON LLP



David P. Creekman, Esq.

Enclosures

Corporate Information

HEADQUARTERS

Furiex Pharmaceuticals, Inc.
3900 Paramount Parkway, Suite 150
Morrisville, NC 27560
Tel.: +1-919-456-7800

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Deloitte & Touche LLP

STOCKHOLDER INQUIRIES

Inquiries from stockholders and other interested parties regarding our Company are always welcome. Please direct your requests for information to: Sailash Patel
Tel.: +1-919-456-7814
Email: Sailash.Patel@furiex.com

STOCK EXCHANGE

Our common stock is listed on the Nasdaq under the symbol FURX.

INVESTOR RELATIONS

Furiex Pharmaceuticals, Inc.
3900 Paramount Parkway, Suite 150
Morrisville, NC 27560

Sailash Patel
*Vice President,
Strategic Development*

Tel.: +1-919-456-7814
Email: Sailash.Patel@furiex.com

STOCK TRANSFER AGENT

American Stock Transfer &
Trust Company, LLC
6201 15th Avenue
Brooklyn, NY 11219
Toll free: +1-800-937-5449
Local and International: +1-718-921-8124
Email: info@amstock.com
website: www.amstock.com

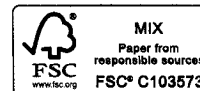
ANNUAL MEETING

The 2012 annual meeting of stockholders will be held on Thursday, May 24th, 2012 at 9:00 a.m. at: The Umstead Hotel
100 Woodland Pond Drive
Cary, NC 27513

WEBSITE

www.furiex.com

This Annual Report includes forward-looking statements. All statements other than statements of historical facts are forward-looking statements, including any projections of milestones, royalties or other financial items, any statements of the plans and objectives of management for future operations, any statements concerning research and development, clinical development timelines, proposed new products or licensing or collaborative arrangements, any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as "believes," "might," "will," "expects," "plans," "anticipates," "estimates," "potential" or "continue," or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained in this Annual Report are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including the risk factors set forth in Item 1A, and for the reasons described elsewhere in the 2011 Form 10-K, any of which could significantly adversely impact our business. All forward-looking statements and reasons why results might differ included in this Annual Report and the 2011 Form 10-K are made as of the date hereof, and we assume no obligation to update these forward-looking statements or reasons why actual results might differ.





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